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FDA Consumer Update

July 1982

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Office of Consumer Affairs (HFE-20)
5600 Fishers Lane
Rockville, Maryland 20857

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Dear Consumer:

The main objective of the Consumer Update is to inform consumers of the many opportunities that are available for participation in the workings of the Food and Drug Administration and in the regulatory process itself. FDA considers public involvement in the early stages of policy formulation to be an important part of effective and responsive regulation, and encourages such participation.

There are several important upcoming opportunities for consumer participation. On September 29, a public hearing will be held on the Agency's "exclusivity" policy to limit the terms that may be used on an OTC drug product's label to the specific terminology included in the applicable OTC drug monograph (see page 18). On September 16, a public legislative-type hearing will be conducted on FDA's proposed recommendations on the Controlled Substances Act scheduling of marihuana plant materials (page 21). FDA has requested public comment on the proposed rule concerning the declaration of sodium, and label claims for foods on the basis of sodium content (pages 1 and 24; Note: The comment period has been extended to November 15).

FDA has published a final regulation to require that tampon package labels carry a warning about their link with the sometimes fatal toxic shock syndrome. The regulation will take effect on December 20, 1982 (pages 10 and 27). The Agency is currently establishing new labeling requirements for drugs containing salicylates. The use of salicylates (such as aspirin) in children with influenza, chickenpox, or certain other viral infections has been sufficiently associated with Reye's Syndrome to warrant a warning to physicians and parents (page 3).

If you have any suggestions on how this document can be more useful to you, please contact me at the Office of Consumer Affairs (HFE-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone 301-443-5006 or TTY (for the deaf) 301-443-1818.

Sincerely yours,

Alexander Grant

Alexander Grant
Associate Commissioner for
Consumer Affairs

HE 20.4010/3:

FDA Consumer Update

Activities and Information

SODIUM LABELING

On June 18, the Food and Drug Administration published in the Federal Register a proposed rule concerning the declaration of sodium content of foods and label claims for foods on the basis of sodium content. The purpose of this is to amend the food labeling regulations to provide more sodium information to consumers so that they can make wise food choices.

The proposed regulations define terms denoting levels of sodium and specify the maximum levels of sodium that a serving may contain when these terms are used on the product label.

FDA is proposing that the term **sodium free** apply only to those foods which contain **5 mg.** or less of sodium per serving. The Agency feels that the establishment of a definition for a "sodium free" food would be useful to the consumer, would assist patients on sodium-restricted diets, and would provide an incentive to industry to 1) make available foods containing trivial amounts of sodium and 2) further reduce the sodium content of some foods which are already low in sodium.

The term **low sodium** would apply to those foods which contain **35 mg.** or less of sodium per serving. A person on mild to moderate sodium restrictions can thus consume "low sodium" foods, as FDA proposes to define them, almost at will without exceeding dietary restrictions.

FDA is proposing that the term **moderately low sodium** apply only to those foods that contain **140 mg.** or less of sodium per serving.

We recognize that there are many foods which, through special processing, have significantly lower sodium content than those for which the reduced sodium foods serve as direct replacements. With the establishment of the above terms, the term **reduced sodium** would be useful for foods which still contain more than 140 mg. of sodium per serving after sodium reduction. Because these products would still contain significant amounts of sodium, a substantial reduction in the level of sodium would be necessary to justify a claim. Therefore, FDA is proposing that the term **reduced sodium** be used only on the labels of foods that have achieved at least a **75 percent reduction** in sodium content over foods for which the reduced sodium foods serve as direct replacements.

The proposed regulations provide for product comparative statements as long as the sodium content is at least 10 percent less than the regular product. They also permit the appropriate use of the terms **unsalted, without salt**

added, and **no salt added** when the product substitutes for another food that is normally processed with salt.

These rules require the declaration of the sodium content on food labels which contain nutrition information. Nutrition information is required if a processor adds nutrients to a product or makes nutritional claims about it. However, the voluntary inclusion of salt/sodium information on a product label does not require the manufacturer to provide full nutrition labeling. In addition, the Agency is recommending the voluntary inclusion of potassium content information in nutrition labeling because people with kidney and some other diseases who must control their sodium intake must also control their potassium intake. Also, people with high blood pressure and other related health problems often use potassium in place of sodium.

Many major food manufacturers have voluntarily included sodium information on food labels since FDA began its sodium education program last year. It is estimated that in 1983 more than one-third of the processed foods FDA regulates will bear voluntary sodium labeling, compared to only 13 percent in 1981. In addition, several manufacturers are marketing (or considering) foods that are lower in sodium, and some are conducting sodium education campaigns.

Written comments on this proposed rule may be submitted before August 17 to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

OIL OF CLOVES

A panel of non-governmental dental and scientific experts has reported to the Food and Drug Administration that oil of cloves, a nonprescription drug, is safe and effective for temporary use on a tooth with persistent throbbing pain. This report is part of a Food and Drug Administration review of all nonprescription drug products currently on the market.

The report stated that of all the 12 active ingredients in common toothache remedies, only clove oil, or a similar oil containing 85 to 87 percent eugenol (a derivative of cloves), is a safe and effective ingredient for toothache. Even this ingredient, however, should be used only temporarily while awaiting a dentist's care, and only on a tooth with "persistent throbbing" pain. With this kind of pain, the tooth pulp is already irreversibly damaged, the panel reasoned, so topical pain-killing products can't cause injury. But pain that is occasional or intermittent is characteristic of reversible damage, and these products should not be used in this case because they could injure the pulp.

The panel also found that the commonly used ingredient benzocaine "appears to be an ideal surface anesthetic" for relieving gum soreness and injury. The panel listed benzocaine and various phenol preparations as safe and effective not only for adults but also for teething infants over four months of age.

The panel's report was published in the May 25 Federal Register. After reviewing public comments on the report, the FDA will propose standards for products promoted for nonprescription use for tooth pain.

ASPIRIN AND REYE'S SYNDROME

Medical experts have concluded that the use of salicylates (such as aspirin) in children with influenza, chickenpox, or certain other viral infections has been sufficiently associated with Reye's Syndrome to warrant a warning to physicans and parents. Reye's Syndrome is a rare, acute, life-threatening condition characterized by vomiting, and lethargy which may progress to delirium and coma in children who are recovering from viral infections, particularly influenza or chickenpox.

The Food and Drug Administration is undertaking an educational campaign aimed at medical care personnel, pharmacists, and parents, and will require that the labeling of these products include a warning against their use in these childhood diseases. Parents should consult their physicians about alternative methods of treatment.

For several years reports have cited the possible association of Reye's Syndrome and the prior use of common medications. During the past two years reports from four case control studies suggested an association between the prior ingestion of salicylates (aspirin and others) and Reye's Syndrome. On the basis of these reports and the recommendations of an advisory panel, on February 12, 1982 the Centers for Disease Control (CDC) advised physicians and parents of the possible increased risk of Reye's Syndrome associated with the use of salicylates for children with chickenpox and influenza-like illness. CDC estimates that 600 to 1200 cases of Reye's Syndrome occur annually in the U.S., and most patients are between the ages of 5 to 16. Death results in 20-30 percent of the cases, with permanent brain damage in many others.

In February an FDA working group began analyzing the raw data from three of the four studies. The working group's preliminary report is dated May 18, 1982. In May an open public meeting, sponsored by FDA, CDC, and the National Institutes of Health was attended by invited experts from the academic community, the drug industry, and consumer organizations to discuss FDA's preliminary analysis of the data. Several of the scientific experts concluded that the new analysis supported the earlier evidence of the association between salicylates and Reye's Syndrome and warrranted the warning to health professionals and parents.

In addition, the American Academy of Pediatrics' Committee on Infectious Diseases also reviewed the data. The June issue of Pediatrics contained a statement advising that the use of salicylates should be avoided in children suffering from influenza or chickenpox.

The Food and Drug Administration has notified health professionals through its Drug Bulletin (which is distributed to over 1 million health professionals), and is establishing new labeling requirements for drugs containing salicylates.

ORAFLEX

On June 17, Ralph Nader's Health Research Group (HRG) petitioned HHS Secretary Schweiker to ban the arthritis drug benoxaprofen, manufactured by Eli Lilly Co. under the brand name Oraflex. In the petition HRG cited a "rapidly increasing number of reports of deaths due to liver and kidney damage in people using this drug."

HRG said British medical journals have reported 12 deaths among Oraflex users ranging in age from 57 to 88 years of age. FDA has been aware of these adverse effects with Oraflex since late May 1982 when Lilly reported the injuries to FDA. They were all reported after FDA approved the drug on April 19, 1982. The Agency believes seven deaths may be traced to the use of Oraflex. The elderly may be more at risk. In the reported deaths, the administered dose was higher than that recommended in the United States package insert. Therefore, Lilly changed the label to emphasize the reduced dosage and notified physicians. FDA has approved a 300 mg. tablet to make it easier for patients to take the lower recommended dose.

It is not yet clear whether these reports indicate an unusually great potential for liver injury by Oraflex because:

- o the case reports are scanty and details (other therapy, other diseases, and kind of patient monitoring) need to be obtained;
- o on occasion, the entire class of drugs appears to cause liver injury;
- o many of the patients already had other diseases besides arthritis, including liver and kidney disease; and
- o most patients had been taking other drugs in addition to Oraflex.

The FDA Arthritis Advisory Committee met in June and discussed liver problems associated with non-steroidal anti-inflammatory drugs (NSAIDs), a class of drugs that includes Oraflex. FDA has asked manufacturers of all NSAIDs, not just Oraflex, to revise their labeling to include a general precautionary statement that liver toxicity does appear to be associated with this class of drugs. The committee also called for more information on the liver toxicity problems associated with the drug class. FDA has the committee's recommendations under study, and is monitoring the drug on a daily basis.

Note: As we go to press, the United Kingdom has suspended distribution of Oraflex for 90 days and Lilly has just announced that it is halting sales and distribution of the product in the United States.

FDA APPROVES FIRST GENITAL HERPES DRUG

On March 30, 1982 the FDA announced approval of acyclovir ointment, the first drug to help manage genital herpes. Though not a cure, it has been shown in tests to shorten the episodes of the disease, which affects 15-20 million Americans. The drug is marketed by Burroughs Wellcome Company under the trade name Zovirax.

The two most common herpes viruses are called herpes simplex Type 1 and Type 2. Type 1 mainly causes cold sores. Type 2 is the major cause of genital herpes and is usually transmitted through sexual contact.

In studies of the drug, female patients with initial infection of genital herpes had speedier healing of sores and reduced virus growth. There was, however, no significant decrease in the pain. In male patients with initial infections of the disease, the studies also showed a significant decrease in the healing time of sores, and in the pain associated with the disease. However, acyclovir did not show important benefits in either men or women with recurrent genital herpes. Acyclovir is also approved for use in patients with herpes attacks resulting from the suppression of their immune systems, as in cancer chemotherapy. It was found to significantly reduce the multiplication of the virus in these patients, and to reduce the duration of pain. The United States is the first country to approve the drug for herpes.

* * * *

NOTE -- Symptoms of genital herpes usually occur within two to ten days after exposure through sexual contact, and generally include tingling, itching and, particularly in women, a painful, burning sensation during urination. Within about one week, women usually develop clusters of small, painful blisters in the vagina, cervix, urethra, sometimes in the anal area, and on the external genitalia. Men get similar sores on the penis and sometimes on the buttocks. Both women and men may have fever, swollen lymph glands in the groin, back pain, stiff neck, and headache. It is not known what causes recurrences of Type 2 herpes, but some victims suffer new attacks very frequently after the first infection while others rarely or never have subsequent attacks.

BONEMEAL

On June 21, the Food and Drug Administration announced results of a nationwide survey of bonemeal products (powder, capsules, and tablets) for lead content. An analysis of 77 samples from forty manufacturers and several importers showed an average lead level of 4.4 parts per million (ppm), with a range of 0.045 ppm to 12.8 ppm.

Bonemeal is used primarily as calcium and/or phosphorus supplements. Bonemeal supplements containing more than 5 ppm lead are of special concern to FDA because they could be used as a source of calcium for young children and by pregnant and nursing women. A 10 gram daily dose of bonemeal (about 3 teaspoonfuls) containing 5 ppm of lead results in an intake of 50 micrograms. The FDA acceptable maximum daily intake from all sources is 100 micrograms for infants, and 150 micrograms for children between six months and two years. Fetuses, infants, and children are the most susceptible to lead toxicity since they tend to absorb lead more readily than adults. FDA is also concerned that some individuals may double or triple the recommended label dosage and thus greatly increase their exposure to lead.

FDA urges, therefore, that bonemeal be used "as little as possible" in diets of pregnant or nursing mothers, infants, and young children. All ages are at risk, however.

The Health Hazard Evaluation Board of FDA's Bureau of Foods continues monitoring lead content in bonemeal preparations. The Bureau will report the findings to the industry so that lead levels may be reduced.

This information was addressed to physicians and other health professionals in the April 1982 issue of the FDA Drug Bulletin.

WEIGHT REDUCTION DIETS

Many consumers write to FDA seeking advice on the various diets that are continually advertised and promoted by authors, publishers, and bookstores. This subject is a popular one for the Consumer Inquiries Staff of the Office of Consumer Affairs (OCA).

Some of the diet books are best sellers, but are their claims and reasonings factual and fair? Although FDA is responsible for assuring the safety of foods and their appropriate labeling, the Agency cannot assure the safety and appropriateness of claims made in articles or books. Only if a book or article is used to misbrand a particular food can FDA regulate its use. Authors, even those without a nutritional or medical background, can make dietary claims that would appear to substantiate or give credibility to the claims.

Many consumers do not know that the First Amendment to the Constitution places certain statements about food and nutrition beyond the reach of Federal regulation through its protection of free speech and free press. Unfortunately, these rights are sometimes abused by people who want to make a profit. Books and articles are often written to "sell" rather than to educate.

Consumers, then, must protect themselves from potentially harmful diets. One way to do this is to consult a physician, dietitian, or nutritionist prior to embarking on any diet. Consumers can also educate themselves by reading nutritional texts and material available in libraries. The following information on some of today's popular diets may prove helpful.

The Cambridge Diet: This is one that currently generates a great many inquiries for OCA. This diet involves drinking a flavored powder mixed with water three times a day, totaling a daily intake of 330 calories. Nutrition experts agree that diets of less than 800 calories a day should not be attempted without frequent medical supervision. Total dependence on as few as 330 calories a day for an extended period of time may result in serious adverse effects. FDA is investigating several cases associated with this diet in which acute illness required hospitalization.

In 1977 FDA issued a public warning about the hazards of very low calorie protein diets, and the Agency continues to believe that the products used in these diets should carry warning labels about the potential health problems associated with their use. A few years ago the U.S. Postal Service brought suit against the distributors of the Cambridge Diet, alleging false and fraudulent claims in the advertising and promotion of the product. In resolving the suit, the defendants agreed to remove claims of exaggerated weight loss, and agreed to include warning statements in their advertisements.

The Stillman Diet: In The Doctor's Quick Weight Loss Diet, I.M. Stillman claims that his high protein (virtually no carbohydrates) diet will cause the "system to burn more calories daily than with a diet of the same total caloric intake that includes other foods." Because most of the loss is water, not body fat, many dieters find that much of the weight loss from this type of diet is regained soon after normal eating is resumed.

The Pritikin Diet: Almost the exact opposite of the high protein diet is a food plan published by Nathan Pritikin. Pritikin claims his plan is primarily aimed at the prevention or treatment of high blood pressure, diabetes, and other diseases, but it includes a weight loss plan that is a 1,000 calorie diet with very limited protein. It is high in complex carbohydrates and low in fats, cholesterol, sugars, salt, coffee, tea, and alcohol. The scientific community appears to be divided in its assessment of the Pritikin plan.

The Mayo Diet: This diet (with which the famed Mayo Clinic denies any association) instructs dieters to eat grapefruit before each meal and then literally stuff themselves with bacon, eggs, meat, fish, and vegetables. The diet is based on the erroneous theory that grapefruit contains enzymes that somehow subtract calories by increasing the fat-burning process.

The Beverly Hills Diet: Judy Mazel's Beverly Hills Diet book combines sound health advice (limited sodium) with trendy ideas (use of bran and raw butter). Basically, this is a low calorie fruit diet based on the theory that protein and carbohydrate digestive enzymes cannot work together. A process Mazel calls "conscious combining" must be used and involves eating proteins only with other proteins, fats and carbohydrates only with other carbohydrates and fats, and fruits alone. An article in the Journal of the American Medical Association notes that "there is no scientific evidence to support this diet, but it also contradicts established knowledge about nutrition." Some professionals have cautioned that the diet has the potential to cause such side effects as diarrhea, gout, kidney stones, heart problems, and strokes.

On June 8, 1982, FDA proposed labeling on certain protein diet products to warn that their misuse can be fatal. Under the proposal, food products deriving more than 50 percent of their calories from protein and promoted for weight reduction would have to carry the following label: "WARNING: Very low calorie protein diets (below 400 calories per day) may cause serious illness or death. DO NOT USE FOR WEIGHT REDUCTION WITHOUT MEDICAL SUPERVISION. Not for use by infants, children, pregnant or nursing women."

Weight loss depends on a reduction in caloric intake over a period of time. For the most part, the most effective way to lose weight and to maintain the lower weight is to eat a balanced diet consisting of smaller amounts of ordinary foods. If you are considering a weight loss program, FDA suggests that you first consult your doctor, who should be able to advise you how to safely and effectively alter your diet.

STARCH BLOCKERS

The Food and Drug Administration has asked more than 100 manufacturers and distributors of "starch blockers" to discontinue marketing them until scientific testing confirms the safety and effectiveness of these weight management products. The FDA action was prompted by users' complaints of nausea, vomiting, diarrhea, and stomach pains.

Starch blockers are prepared from raw beans (such as kidney, northern, or other types) and possibly from other unknown ingredients; they contain an extract that supposedly inhibits the body's production of the intestinal enzyme amylase that helps digest starch.

These products are advertised and sold nationwide with claims that they block or impede starch digestion and thus help in weight control and weight reduction by preventing the absorption of carbohydrates. According to some claims, users can eat generous helpings of bread, potatoes, and other starchy foods without concern about their waistlines because much of the starch will pass through the intestines undigested.

FDA has asked starch blocker manufacturers for specific information about the exact chemical composition of these products. This information has been refused. Nor does the Agency have any data supporting claims of safety or effectiveness in weight control or weight reduction.

In addition to follow-up to the claims of adverse reactions from the starch blockers, FDA is concerned about the consequences for tablet users who have health problems. For example, the failure of starch blockers to perform as expected could prove hazardous for diabetics who rely on them to help keep down blood sugar levels. NOTE: Persons with diabetes should not depend on starch blockers in calculating their diets.

Some manufacturers claim that starch blockers are a form of special dietary food. However, because their claimed effect is weight control or reduction by their action to block, or interfere with, digestion, they can be considered to affect the body's normal metabolism. Under the Federal Food, Drug, and Cosmetic Act, a substance that is offered for a nonfood purpose and that alters a function of the body is classified as a drug, rather than a food, even if it is derived from a vegetable product. Therefore, these starch blockers are considered to be "unapproved new drugs."

FDA requested the firms involved with the starch blockers to discontinue marketing them and to furnish specific information about their manufacture and distribution. If the firms fail to comply they will be subject to regulatory action. Such action could include court-ordered seizures and/or injunctions to cease further manufacture and sales.

On July 9, eight health food producers and marketers filed suit in federal court in New York to prevent FDA from classifying starch-blocker weight-control products as drugs. The companies are seeking a declaratory judgement to compel the Agency to classify the products as food supplements. Similar federal suits have been filed by health food manufacturers and distributors in Chicago. FDA intends to defend its July 1 decision to declare these products as drugs.

In the meantime, consumers are urged to stop taking these products until their safety and effectiveness can be substantiated.

BENZYL ALCOHOL LINKED TO DEATHS OF PREMATURE INFANTS

Two new studies suggest that benzyl alcohol, a long-term preservative in some vials of sterile saline and water used intravenously, may have been linked to the deaths of 16 low-weight premature infants. Because these infants already had medical problems requiring intensive care (breathing support and intravenous feedings and medicines), the additional burden posed by the preservative was not previously recognized. FDA has received no reports of problems in older infants, children, or adults.

FDA wrote to advise pediatricians, hospital pharmacists, and hospital administrators that comparable products not containing the preservative are available. The FDA letter cited research at the Southern Baptist Hospital, New Orleans, La., and the Oregon Health Sciences University-Doernbecher Memorial Hospital for Children, Portland.

The researchers identified ten premature infants in Portland and six in New Orleans whose deaths followed a pattern of gasping, respiration, unresponsiveness, and sometimes seizures. This pattern was linked to a finding of benzyl alcohol or its breakdown in the infants' urine or blood. The substance is often contained in solutions used for flushing an intravenous or arterial catheter after blood samples are drawn. (The same catheter may be used for feeding and medicating these infants and must be flushed after being used to obtain blood samples.) Benzyl alcohol may also be used to maintain the sterility of injectable solutions intended for multiple administrations.

FDA is working with manufacturers, the U.S. Pharmacopeia, the American Academy of Pediatrics, the American Society of Hospital Pharmacists, the American Nurses Association, and others to inform health professionals caring for small babies about the new information.

TOXIC SHOCK SYNDROME

On June 22 the Food and Drug Administration published in the Federal Register a final regulation to require that tampon package labels carry a warning about their link with the sometimes-fatal illness toxic shock syndrome.

The regulation, which will take effect on December 20, 1982, requires a comprehensive statement on the package or a shorter alert advising users to read an information leaflet inside the package. The shorter alert reads: "ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information."

Studies by the Centers for Disease Control (CDC) and several State health departments first associated toxic shock syndrome with tampon use in 1980. When FDA proposed a warning label for tampons, it received 344 comments from consumers and consumer organizations, manufacturers, trade associations, and state and local health agencies, almost all in support of some form of TSS package labeling. CDC has received reports of more than 1,660 cases of TSS, including 88 deaths. About 50 cases of TSS are reported to CDC each month.

Although manufacturers have voluntarily included information about TSS in or on tampon packages since 1980, this regulation will provide consistency in the kind of information that is distributed. FDA believes that the warning labels will provide important information to help women protect themselves against the dangers of tampon-associated toxic shock syndrome.

The regulation requires the manufacturer to make several points in clear language either on the package or inside:

- the warning signs of TSS, e.g., sudden high fever (usually 102°F or more), and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;
- what to do if these or other signs appear, including the need to remove the tampon at once and seek medical help immediately;
- the risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 6 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;
- the advisability of using tampons with the minimum absorbency needed to control menstrual flow;
- the possibility of avoiding the risk of getting tampon-associated TSS by not using tampons and reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and
- the need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

COMMITTEE ON PATIENT INFORMATION UPDATE

In January 1982, Commissioner Hayes appointed the Committee on Patient Information (COPE) to coordinate the government's efforts to educate consumers about prescription drugs, and to serve as a catalyst for private sector initiatives in this area.

In the April 1982 Consumer Update, we summarized the early meetings of the Committee on Patient Education. These meetings included an AMA presentation on its proposal to provide Patient Medication Instruction leaflets to patients through physicians, and Ciba-Geigy Corporation's plan to provide $1 million toward the funding of a Joint Commission on Patient Education. We also reported on FDA's efforts to advertise the need for patient education and to encourage groups outside the government to help us in the effort. See the April 1982 Update for reports on other COPE meetings.

The Committee has continued to meet with private groups interested in patient education.

- On May 4, Retired Persons Services, Inc., the pharmacy service of the American Association of Retired Persons, described to COPE its plan to provide patient package inserts for the prescriptions it fills. The AARP pharmacy service serves about 14 million retired Americans through ten regional mail-order pharmacies. The inserts are now being provided for five drugs; 15 more will be covered soon. The pharmacy service plans to develop 40 to 50 leaflets that represent about 75 to 90 drugs or drug classes. FDA staff worked with AARP in designing these leaflets.

- On May 27, the Committee met in executive session to discuss issues related to FDA preparation and evaluation of patient education materials. The members agreed that FDA would not duplicate private sector activities by producing patient education texts for all drugs, but that the Agency could assist private efforts where a clear need exists for such texts. The members also agreed that FDA did not have the resources to review all privately-produced patient education materials, but would try to help organizations that ask for assistance. Also, FDA will continue to work with drug manufacturers to assure effective, accurate labeling for their products.

- Also on May 27, a COPE subgroup met with representatives of Biomedical Information, Inc. (BII), a New York-based publisher. BII produces the Compendium of Drug Therapy, a compilation of drug information to advise physicians about the drugs they prescribe. The company is now planning to distribute, free of charge, a companion volume that will contain patient information. The volume will have perforated pages for ease of removal by the doctor to give to the patient.

FIRST "FAST TRACK" DRUG APPROVED

In February 1980, FDA's Bureau of Veterinary Medicine (BVM) established the "Fast Track" system to speed important new drugs through the review and approval process. In order to qualify for this priority review handling, a drug must:

- o be a new molecular entity -- i.e., the active component must never have been marketed in the United States for use in the animal species; and

- o present either an important therapeutic gain (by providing greatly increased effectiveness or safety in the treatment or prevention of a disease not adequately treated or prevented by any marketed drug or providing improved treatment or prevention through improved effectiveness or safety), or present a modest therapeutic gain (by providing a modest, but real potential advantage over other available marketed drugs -- e.g., more convenient administration, elimination of an annoying but not dangerous adverse reaction).

The Fast Track system is intended to make as many new animal drug application (NADA) decisions as possible during the investigational new animal drug (INAD) phase. In this way, the formal processing of the NADA should require only a minimum amount of time and involve primarily administrative matters and final label review. Fast Track processing does not mean a relaxation of any of the scientific requirements, but rather that the data submitted in support of an NADA will receive priority review. The objectives of the Fast Track system are to:

- o demonstrate as rapidly as possible if the product is safe and effective and if the manufacturing controls are adequate; and

- o keep at a minimum, the utilization of personnel and paperwork by the sponsor and FDA.

The first drug approved through this system was Mitaban Liquid Concentrate. Manufactured by the Upjohn Co., the product is a dip solution for treating dogs for generalized mange caused by demodectic mites. Generalized demodectic mange has been a difficult disease to treat. The chemical involved -- amitraz -- is a new drug entity which provides an important therapeutic gain. Data supporting the Mitaban application indicate that the drug is uniquely effective in treating the disease.

The NADA for Mitaban had been submitted in July 1979 -- before the Fast Track system had been established. Immediately after initiating the program, the application was granted Fast Track status. Following the final submission in January 1982 of data adequately documenting the safety/efficacy of the product, the Fast Track system enabled rapid processing until Mitaban's approval on April 30, 1982.

BENDECTIN

Bendectin, the only prescription drug approved since 1956 for the relief of nausea and vomiting of early pregnancy, is the center of a controversy about its potential to cause fetal birth defects. The drug, manufactured by Merrell-Dow Pharmaceuticals, Inc., is a fixed combination of two ingredients, doxylamine succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B_6). Doxylamine is also available in several over-the-counter cough-cold preparations and a nighttime sleep aid, Unisom. The label for the latter warns against use by pregnant women.

On June 25, the Public Citizens Health Research Group (HRG) petitioned Health and Human Services Secretary Schweiker to immediately remove from the market Bendectin and all other fixed-combination drugs containing these two ingredients. The HRG petition cited new animal studies and a review of human data.

A controlled rat and mouse study conducted by the West German Health Ministry showed an increased frequency of diaphragmatic hernia (a hole in the muscle separating the chest and abdominal cavities). Fetuses of 2-5.9% of rats given Bendectin developed hernias; fetuses of a control group showed none. An additional animal study, not cited in the HRG petition, was conducted in monkeys at the University of California. This study found heart defects (e.g., a hole between two chambers of the heart) in 4 of 7 fetuses of Bendectin-treated mothers. The rat and monkey studies are being repeated.

As recommended in September 1980 by an expert advisory committee, FDA continues to monitor the safety of Bendectin. The drug is now indicated for use only in those patients with significant nausea and vomiting unresponsive to more conservative measures (such as eating soda crackers or drinking hot or cold liquids upon awakening). The firm will conduct a new clinical trial to determine the degree of effectiveness in those patients.

After evaluating data from 13 epidemiological studies and FDA's adverse reaction reporting system, the committee concluded that the available data did not demonstrate an association between an increased risk of birth defects and the use of Bendectin, but that a "residual uncertainty" did exist. However, the committee noted that none of the studies were of sufficient size to detect doubling of a specific malformation. FDA is currently reviewing additional human data on the association of diaphragmatic defects.

The Food and Drug Administration has met with the firm to review and revise the current labeling to inform physicians of the latest animal studies. The firm will make the drug available in a new "Unit-of-use" package with a patient package insert (PPI). The current PPI states "Because it is not possible to prove that a drug taken by a pregnant woman does not, on rare occasion, cause birth defects, Bendectin should be taken only when clearly needed. Although this leaflet cautions about the use of Bendectin, this drug has been the most carefully studied of all drugs that could be used to treat the nausea and vomiting of pregnancy."

FDA advises pregnant women who have questions to read the leaflet and consult their physician before taking this drug.

FDA ADVISORY COMMITTEE CONSUMER REPRESENTATIVE

FDA advisory committees are composed of panels of outside experts who consider issues related to the premarket approval or disapproval of drug, medical device, radiological, and biological products. Offering a unique combination of scientific/technical expertise and consumer credentials to committee deliberations, consumer members serve on 35 FDA advisory committees.

In the April 1982 Consumer Update we initiated a series of profiles on consumer members and the work of their committees. In this edition of the Update, we are providing the following profile of Estelle Greene, a consumer member of the General Hospital and Personal Use Section, General Medical Devices. The profile is provided to encourage direct interaction between the public and the consumer advisory committee members.

The General Hospital and Personal Use Section reviews premarket approval applications for medical devices used in the hospital and for personal use, ranging from bedside devices used during surgery, labor, and delivery to drug infusion devices. Recently, this committee considered the safety and effectiveness of an implantable drug pump which administers steady, continuous drug therapy to an affected site. FDA approved its use to deliver an anti-cancer drug, fluoruridine, directly to a cancer-ridden liver and to dispense heparin to prevent clots and treat disorders such as phlebitis.

Estelle Greene, a consumer leader from the Miami, Florida area, serves on this panel as a consumer representative. She has contributed significantly to the development of the following recommendations:

- The ID card used by patients with an implantable drug pump should be revised to include additional information which could be important in an emergency situation.
- When evaluating portable devices, panel members should be provided the actual device for examination rather than just a photograph.
- Training films in the use of the biostator glucose controlled insulin infusion system should be made available for hospital personnel.
- A speaker from FDA's Bureau of Radiological Health should be present at a future panel meeting to discuss the safety aspects of the use of a transcutaneous bilirubin meter to indicate the presence of jaundice in newborn infants.

In order to develop a stronger consumer network, Ms. Greene is interested in discussing with individuals and groups consumer concerns related to General Medical Devices. Being closely involved with the consumer community in the Miami area, she participated as a panelist in the South Florida Health Systems Agency discussion of the consumers' role in the assessment of medical care. Ms. Green is active in promoting drug education for the elderly and has distributed large quantities of FDA publications to the elderly on the proper use of medicines. She is an active member of the American Association of University Women-Miami Branch. In 1981 she was selected for membership in the Health Systems Agency of South Florida as an individual member. If you have any information related to the work of this committee, please contact her at the following address: Ms. Estelle Greene, 5450 SW 63 Court, Miami, Florida 33155, (305) 667-2433.

INFANT APNEA MONITORS: CONSUMER EXPERIENCE REPORTING

An article in the April 1982 Consumer Update identified problems associated with the use of infant apnea monitors, which are devices used to detect apnea. Apnea is a condition in which an individual's respiration stops for more than 10 seconds either because of airway blockage, a loss of neural control, or a combination of both. In that article, we asked you to send information about apnea monitors to FDA. We again would like to encourage you to report your experiences with infant apnea monitors and ask you to send information which relates to the questions below to:

Mr. Frank Houston (HFK-310)
Food and Drug Administration
Bureau of Medical Devices
8757 Georgia Avenue
Silver Spring, MD 20910

- What make and model did you use?
- Did you buy or rent the monitor?
- Did you decide to monitor and choose the particular monitor based on a doctor's recommendation?
- Were you enrolled in a home-monitoring project group and did you receive any infant cardiopulmonary resuscitation (CPR) training?
- What problems did you have with the device?
- What features did you like, and what features did you dislike or believe should be improved?
- How long did you use the monitor?

*ADVERSE EXPERIENCES with apnea monitors should also be reported to FDA's medical device Problem Reporting Program (PRP). An article describing the PRP appears on pages 9-11 of the April 1982 issue of the Update.

District Consumer Exchange Meetings

Nashville, TN
When: August 25, 1982, 10:00 a.m.
Where: FDA, 297 Plus Park Blvd., Nashville, TN
Contact: Barbara Shields, Consumer Affairs Officer, 615-251-7127

Nashville, TN
When: August 27, 1982, 11:00 a.m.
Where: 220 Bicentennial Blvd., Lawrenceburg, TN
Contact: Jessica A. Parchman, Consumer Affairs Officer, 615-251-7127

New York, NY
When: September 15, 1982, 9:30 a.m.
Where: FDA, 850 Third Avenue, Brooklyn, NY
Contact: William E. Martinez, Consumer Affairs Officer, 212-965-5043

National Consumer Exchange Meeting

Washington, DC
When: September 13, 1982, 3:30 p.m.
Where: Hubert H. Humphrey Building Auditorium
200 Independence Avenue, S.W.
Contact: Naomi Kulakow, Director, Public Participation Staff, 301-443-5006

Directory

LOCATIONS WITH CONSUMER AFFAIRS OFFICERS

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Phone: (301) 962-3731

Boston, MA 02109
585 Commercial Street
Phone: (617) 223-5857

Brooklyn, NY 11232
850 Third Avenue
Phone: (212) 965-5754
(212) 965-5043

Buffalo, NY 14202
599 Delaware Avenue
Phone: (716) 846-4483
(716) 846-5452

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433 West Van Buren Street
1222 Main Post Office Building
Phone: (312) 353-7126

Cincinnati, OH 45202
1141 Central Parkway
Phone: (513) 684-3501

Cleveland, OH 44114
601 Rockwell Avenue, Room 463
Phone: (216) 522-4844

Dallas, TX 75202
1200 Main Tower Building
Room 15-45
Phone: (214) 767-5433

Denver, CO 80202
500 U.S. Customhouse
19th and California Streets
Phone: (303) 837-4915

Detroit, MI 48207
1560 East Jefferson Avenue
Phone: (313) 226-6260

East Orange, NJ 07018
20 Evergreen Place
Phone: (201) 645-6365
(201) 645-3265

Falls Church, VA 22046
701 W. Broad Street, Room 309
Phone: (703) 285-2578

Houston, TX 77009
1440 N. Loop, Suite 250
Phone: (713) 226-5581

Indianapolis, IN 46204
975 North Pennsylvania, Room 693
Phone: (317) 269-6500

Kansas City, MO 64106
1009 Cherry Street
Phone: (816) 374-3817

Los Angeles, CA 90015
1521 W. Pico Boulevard
Phone: (213) 688-4395

Miami, FL 33166
6501 N.W. 36th Street, Room 200
Phone: (305) 526-2920

Minneapolis, MN 55401
240 Hennepin Avenue
Phone: (612) 725-2121

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297 Plus Park Boulevard
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Phone: (504) 589-2420

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Phone: (402) 221-4675

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Phone: (305) 855-0900

Philadelphia, PA 19106
Room 900 U.S. Customhouse
2nd and Chestnut Streets
Phone: (215) 597-0837

Pittsburgh, PA 15220
7 Parkway Center, Suite 645
Phone: (412) 644-2858

San Antonio, TX 78204
419 S. Main, Room 301
Phone: (512) 229-6737

San Francisco, CA 94102
50 United Nations Plaza, Room 524
Phone: (415) 556-2682

San Juan, PR 00905
P.O. Box S4427
Old San Juan Station
Phone: (809) 753-4465

Seattle, WA 98174
909 First Avenue
Federal Office Building, Room 5009
Phone: (206) 442-5258

St. Louis, MO 63102
808 North Collins Street
Lacledes Landing
Phone: (314) 425-5021

FDA Consumer Update

Federal Register

ANPR Advance Notice of Proposed Rulemaking
FR Final Rule
N Notice
NA Notice of Availability
PR Proposed Rule
WPR Withdrawal of Proposed Rule

Biologics

General Biological Products Standards FR

FDA is amending the biologics regulations to reflect the requirement that the statement: "Caution: Federal law prohibits dispensing without prescription" be placed on labels of all prescription biologicals. The Agency is issuing the final rule to clarify an existing licensing requirement that has been enforced for many years. **Effective June 24, 1982.** For further information contact: Joseph Wilczek, Bureau of Biologics (HFB-620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.

Docket No. 81N-0133 Federal Register 5/25/82 p. 22518

Designated Names PR

FDA is proposing to revoke the existing list of official names of drugs designated by the Agency. Nonproprietary drug names adopted by the U.S. Adopted Name (USAN) Council will serve as "established names" under section 502(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)) unless FDA designates an official name for a drug because it finds the USAN to be unduly complex or not useful. This action will make it unnecessary for FDA to publish routinely as official names those names of drugs adopted by the USAN Council, and it will not affect the availability to the public of current information on acceptable "established names" of drugs. **Comments by September 14, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Ed Farha, National Center for Drugs and Biologics (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

Docket No. 81N-0263 Federal Register 7/16/82 p. 31008

Source Plasma (Human); Dating Period and Reduction of Record Retention Requirements FR

FDA is amending the biologics regulations by prescribing a 10-year dating period for Source Plasma (Human) and requiring the expriation date on the label for Source Plasma (Human). These amendments will reduce recordkeeping retention while ensuring the safety, purity, and efficacy of the final products. **Effective August 16, 1982,** labeling requirements shall become effective January 12, 1983. For further information contact: Steven F. Falter, National Center for Drugs and Biologics (HFB-620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.

Docket No. 79N-0316 Federal Register 7/16/82 p. 30968

Drugs

FDA Policy Relating to Limitations of Labeling Terminology in OTC Drug Monographs; Public Hearing N

FDA is announcing that a public hearing will be held on the Agency's policy of limiting the terms that may be used in over-the-counter (OTC) drug product's label to the specific terminology included in the applicable final OTC drug monograph. This policy, known as the "exclusivity" policy, has been challenged throughout the OTC drug review process, and the Agency has been petitioned for a hearing respecting the policy's implementation in the context of the nighttime sleep-aid and stimulant drug products monographs. Although interested persons are invited to submit comments on any aspect of the exclusivity policy regarding any OTC drug product, the Commissioner of Food and Drugs will structure the hearing to seek answers to these specific questions:

(1) Does the government have a substantial interest in restricting the terminology used in the labeling of OTC drug products?

(2) If the government's interest is substantial, does restricting labeling to terminology approved by FDA in a final monograph directly advance this interest?

(3) Is the restriction imposed by the exclusivity policy more extensive than is necessary to serve that interest?

(4) By imposing such a restriction, does the Agency exceed its authority under the Federal Food, Drug, and Cosmetic Act?

(5) Is the restriction a prior restraint on free speech that is prohibited by the Constitution?

(6) Should there be limitations on terminology used in the labeling of OTC drug products? If the current policy of exclusivity of labeling should be changed, what changes would be desirable from the standpoints of consumers and marketers?

The following alternatives have been identified:

(a) Provide a separate list of approved synonyms maintained on file in the Dockets Management Branch. This alternative would retain the exclusivity policy but provide a simpler and more expeditious means of obtaining additional acceptable language for use in labeling.

(b) Require specific information to be included in a designated area of a product's labeling without deviation from the approved language, but permit manufacturers to use their own synonymous language outside the designated area. This alternative would preserve the exclusivity policy with respect to claims made in the designated area, thus providing consumers with an FDA-approved source of information on the label itself, while at the same time allowing manufacturers the flexibiltiy to employ reasonable

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interpretive language elsewhere in the product's labeling. The Agency believes that this alternative represents a compromise that may incorporate the advantages of the exclusivity policy while avoiding some of its perceived rigidity.

(c) Allow manufacturers to interpret the claims included in a monograph in synonymous language. This alternative would abandon the exclusivity policy. Manufacturers would still be required to employ accurate, nonmisleading terminology, but would not have to obtain FDA's prior approval for the language chosen.

Written notices of participation must be filed **by August 13, 1982** with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. **The public hearing** will be held on **September 29, 1982,** beginning at 9 a.m., Conference Room D & E, Parklawn Building, 5600 Fishers Lane, Rockville, MD. For further information contact: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 82N-0154

Federal Register 7/2/82 p. 29002

Boil Ointment Drug Products for OTC Human Use ANPR

FDA is issuing an advance notice of proposed rulemaking that would classify boil ointment drug products for over-the-counter (OTC) human use as not generally recognized as safe and effective and as being misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products and is part of the ongoing review of OTC drug products conducted by FDA. **Written comments by September 27, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 82N-0054

Federal Register 6/29/82 p. 28306

Designating a Manufacturer's Name on a Drug Product Label PR

FDA is proposing to amend the regulation setting forth requirements for designating a manufacturer's name on a drug product label to permit a firm to claim to have made a product actually made by a corporately related firm under common ownership and control. The action responds to a petition pointing out various marketing and labeling problems that the current regulation poses for certain diversified corporate structures. The proposed regulation would permit any member of a diversified corporate "family" to claim to have made a product made within the "family". Note -- in the Federal Register of January 13, 1981 (46 FR 2977), FDA announced a stay of those parts of the final rule that would prevent a firm from claiming to have made a product actually made by a corporately related firm. That stay will remain in effect pending resolution of this rulemaking. **Comments by August 9, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Steven Unger, Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.
Docket No. 80P-0437

Federal Register 6/8/82 p. 24735

Drugs

FDA ONGOING REVIEW OF OVER-THE COUNTER (OTC) DRUG PRODUCTS **NPR**

As part of its ongoing review of OTC drug products, FDA is issuing in the Federal Register of 7/9/82 notices of proposed rulemaking in the form of tentative final monographs that would establish conditions under which over-the-counter (OTC) anticholinergic and expectorant drug products, topical otic drug products, and topical antimicrobial drug products are generally recognizd as safe and effective and not misbranded. FDA is issuing these notices of proposed rulemaking after considering the reports and recommendations of the appropriate advisory review panels and public comments on the advance notices of proposed rulemaking that were based on those recommendations.

Anticholinergic Drug Products and Expectorant Drug Products
(anticholinergics are drugs used in cough-cold products for relief of excessive secretions of the nose and eyes, symptoms which are commonly associated with hay fever, allergy, rhinitis, and the "common cold" (cold); expectorants are drugs used to promote or facilitate removal of secretions from the respiratory airways). Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products.

Docket No. 76N-052C, p. 30002.

Topical Otic Drug Products
(products for the ear). Advisory Review Panel on OTC Topical Aneigesic, Antirheumatic, Otic, Burn and Sunburn Prevention and Treatment Drug Products.

Docket No. 77N-0334, p. 30012.

Topical Antimicrobial Drug Products
(first aid antibiotic drug products). Advisory Review Panel on OTC Topical Antimicrobial II Drug Products.

Docket No. 76N-0482, p. 29986.

Written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs on the proposed regulation by **September 7, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. New data by July 11, 1983. Comments on the new data by September 9, 1983. These dates are consistent with the time periods specified in the Agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Written comments on the Agency's economic impact determination by November 8, 1982. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 76N-052C Federal Register 7/9/82 p. 30002

Pediculicide Drug Products for OTC Human Use **ANPR**

FDA is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) pediculicide drug products are generally recognized as safe and effective and not misbranded. Pediculicide

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drug products are used for the treatment of head, pubic (crab), and/or body lice.) This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products and is part of the ongoing review of OTC drug products conducted by FDA. **Written comments by September 27, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

Docket No. 81N-0201 Federal Register 6/29/82 p. 28312

Scheduling Status of Marihuana and Its Components and Notice of Public Hearing N

FDA announces (1) its proposed recommendation, including scientific and medical evaluations, on the appropriate scheduling of marihuana plant materials under the Controlled Substance Act and (2) that the proposed recommendations will be the subject of a public legislative-type hearing to be held on September 16, 1982. The proposed recommendations are published to give interested persons the opportunity to comment on the recommendations and on the scientific and medical evaluations. FDA will consider these comments as well as the information gathered from the public hearing in preparing its final recommendations and scientific and medical evaluations of the marihuana plant materials before transmitting them to the Assistant Secretary for Health, DHHS. The Assistant Secretary for Health is responsible for making the DHHS recommendation to the Drug Enforcement Administration (DEA). **Comments by October 1, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. **Notice of participation in the public hearing by August 27, 1982.** Written or oral notice of participation along with the text or comprehensive outline to the Division of Neuropharmacological Drug Products (HFD-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3800. For further information contact: Edwin V. Dutra, Jr., Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

Docket No. 82N-0162 Federal Register 6/29/82 p. 28141

Erythromycin Estolate WPR

The Commissioner of Food and Drugs announces that he has completed his review of the administrative record concerning the safety of erythromycin estolate. The Commissioner concludes that the drug is safe in that the risks of hepatotoxicity do not outweigh its therapeutic benefits. Accordingly, the Commissioner withdraws a proposal to revoke provisions for certification of adult dosage forms of erythromycin estolate and in a related document published elsewhere in this issue sets forth the labeling changes. In addition, the Commissioner denies a petition requesting that all dosage forms of erythromycin estolate be removed from the market. **Effective May 25, 1982.** The transcript of the public hearing before the advisory committee, evidence and comments submitted, and all other documents listed in this notice may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday. For further information contact: Suzanne O'Shea, Bureau of Drugs (HFD-32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

Docket No 79N-0459 Federal Register 5/25/82 p. 22547

Drugs

Oral Health Care Drug Products for Over-the-Counter Human Use **ANPR**

FDA is issuing an advance notice of a proposed rulemaking that would establish conditions under which over-the-counter (OTC) oral health care drug products (products for use in the mouth and throat) are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Oral Cavity Drug Products and is part of the ongoing review of OTC drug products conducted by FDA. **Written comments by August 23, 1982,** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 81N-0033 Federal Register 5/25/82 p. 22760

Drug Products for the Relief of Oral Discomfort for OTC Human Use **ANPR**

FDA is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) drug products for the relief of oral discomfort (drugs which relieve oral discomfort when applied topically to teeth and gums) are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review panel on OTC Dentifrice and Dental Care Drug Products and is part of the ongoing review of OTC drug products conducted by FDA. **Written comments by August 23, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Reply comments by September 22, 1982. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 80N-0228 Federal Register 5/25/82 p. 22712

Alcohol Drug Products for Topical Antimicrobial OTC Human Use **ANPR**

FDA is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) alcohol drug products for topical antimicrobial use are generally recognized as safe and effective and not misbranded. This notice relates to the development of a monograph for topical antimicrobial drug products in general, which is part of the ongoing review of OTC drug products conducted by FDA. This notice also reopens the administrative record for OTC topical antimicrobial drug products to allow for consideration of recommendations on alcohol drug products that have been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products. **Written comments by August 19, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Reply comments by September 20, 1982. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 75N-0183 Federal Register 5/21/82 p. 22324

Drug Products Containing Pentylenetetrazol **N**

The Commissioner of Food and Drugs denies a hearing and declares all drug products containing pentylenetetrazol either as a single ingredient or in combination with other ingredients to be "new drugs" which are not exempt

Drugs

from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act by virtue of the "grandfather" provisions of the Act. All such drugs require approved new drug applications to be lawfully marketed in interstate commerce. The drugs are offered for a variety of conditions associated with senility and for vertigo. **Effective May 14, 1982.** For further information contact: Paul D. Leber, M.D., Division of Neuropharmacological Drug Products (HFD-120), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4020.
Docket No. 75N-0365 Federal Register 5/4/82 p. 19208

Diphenhydramine; Marketing Status as a Nighttime Sleep-Aid Drug Product for OTC Human Use N

FDA is announcing an enforcement policy to permit the over-the-counter (OTC) marketing of diphenhydramine as an ingredient in nighttime sleep-aid drug products. The enforcement policy will permit the OTC marketing of such drug products pending establishment under the OTC drug review of a final monograph under which drug products containing diphenhydramine that are intended for use as OTC nighttime sleep-aids will be generally recognized as safe and effective and not misbranded. **Effective April 23, 1982.** For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-4434960.
Docket No. 75N-0244 Federal Register 4/23/82 p. 17740

Marketing Status of Ingredients Recommended for OTC Use FR

FDA is amending the statement of the Agency's enforcement policy for over-the-counter (OTC) marketing of drug products containing certain active ingredients that are under consideration in FDA's ongoing review of OTC drugs. The amended policy statement clarifies the authority of the Commissioner of Food and Drugs to permit the interim OTC marketing of drug products containing an active ingredient previously limited to prescription use and classified by an advisory review panel in a category other than Category I (generally recognized as safe and effective and not misbranded) in cases in which the Commissioner subsequently has tentatively determined the active ingredient to be generally recognized as safe and effective. **Effective April 23, 1982.** For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 81N-0370 Federal Register 4/23/82 p. 17738

Weight Control Drug Products for Over-the-Counter Human Use ANPR

FDA is extending to July 26, 1982 the comment period, and to August 27, 1982 the reply comment period for the advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) weight control drug products. This action is being taken in response to a request to allow more time for interested parties to examine background data on the safety of phenylpropanolamine, an active ingredient in weight control drug products, in order to provide more informed comments on the notice. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 81N-0022 Federal Register 4/23/82 p. 17576

Foods

Food Labeling; Declaration of Sodium Content of Foods PR

FDA is proposing to amend the food labeling regulations to (1) establish definitions for the terms "sodium free," "low sodium," "moderately low sodium," and "reduced sodium," (2) provide for the proper use of these terms in the labeling of foods (3) provide for the inclusion of potassium content information in the nutrition labeling format on a voluntary basis, (4) provide for the appropriate use of such terms as "without added salt," "unsalted," and "no salt added," and (5) specify that sodium content of foods be included in nutrition labeling information whenever nutrition labeling appears on food labels. FDA is also issuing a statement of policy on the appropriate use of comparative labeling statements. This proposal is a result of FDA's evaluation of the health aspects of sodium chloride as a food ingredient and FDA's investigation of the public health significance of excessive sodium in the diet. This proposal would encourage meaningful label declarations of sodium and potassium. There has been and continues to be considerable discussion and activity in this area. In the United States House of Representatives there have been several legislative proposals discussed which center on the issue of whether sodium labeling should be mandatory or voluntary. In addition, the food industry has initiated very positive actions to add, as a voluntary matter, sodium labeling. This proposal primarily emphasizes the voluntary addition of sodium information to the food label and provides flexibility on how this information is presented. The definitions discussed herein are applicable only if a manufacturer chooses to promote his product by use of one of the definitions. Based on this proposal, the only foods that must bear sodium labeling are those that must bear nutrition labeling, or those that the manufacturer chooses to so label voluntarily. Nutrition labeling is provided for public health reasons--to assist people in knowing the nutrition content of foods. Because of the public health importance of sodium, such information would be incomplete if it were not included as part of nutrition labeling. It is important to note that the FDA, through a statement of policy contained in this document, is reaffirming the fact that if a manufacturer voluntarily chooses to put sodium information on the label, that act will not trigger full nutrition labeling. **Written comments by August 17, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: F. Edward Scarbrough, Bureau of Foods (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3117.

Docket No. 80N-0314 Federal Register 6/18/82 p. 26580

Food Labeling; Protein Products; Warning Label PR

FDA is proposing to amend a final rule published in the Federal Register of April 4, 1980, that established label warning requirements for certain protein products that may be used to reduce weight. The regulation is being amended in accordance with a decision of the District Court for the District of Columbia. The decision found a part of the regulation to be invalid and remanded the entire regulation to the Agency for revision of those parts of the regulation invalidated by the court. This document proposes amendments to the regulation that are consistent with the court's ruling. **Written comments by August 10, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Victor P. Frattali, Bureau of Foods (HFF-261), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1064.

Docket No. 77N-0404 Federal Register 6/11/82 p. 25379

Foods

GRAS Safety Review of Sodium Chloride N

FDA is announcing its decision to defer any revision in the regulatory status of salt (sodium chloride). Salt is currently considered to be generally recognized as safe (GRAS) for use as an ingredient in food. There is considerable health concern about the levels of use of salt in the food supply. FDA is not now proposing any change in the regulatory status of salt, however, because the Agency believes that the proposed sodium labeling regulations, published elsewhere in this issue of the Federal Register, will respond to those concerns. FDA is also announcing its policy of encouraging food manufacturers to reduce voluntarily the amount of added salt and other sodium-containing substances in processed foods. **Comments by August 17, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Richard C. Kraska, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-4750.
Docket No. 81N-0234 Federal Register 6/18/82 p. 26590

D&C Green No. 5 FR

FDA is "permanently" listing D&C Green No. 5 for use in drugs and cosmetics, excluding use in the area of the eye. This action is in response to a petition filed by the Cosmetic, Toiletry, and Fragrance Association, Inc., the Pharmaceutical Manufacturers Association, and the Certified Color Manufacturers Association, Inc. This rule will remove D&C Green No. 5 from the provisional list of color additives for use in drugs and cosmetics. **Effective July 7, 1982.** For further information contact: Rudolph Harris for general information, and Terry C. Troxell for information relating to the safety evaluation of D&C Green No. 5: Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.
Docket No. 76C-0045 Federal Register 6/4/82 p. 24278

D&C Green No. 6 FR

FDA is confirming the effective date of May 4, 1982, for a final rule that amended the color additive regulations by "permanently" listing D&C Green No. 6 for use in externally applied drugs and cosmetics. That document also provided for the depletion of existing stocks of D&C Green No. 6 for all uses involving ingestion of the color additive. **Effective May 4, 1982.** For further information contact: Garnett R. Higginbotham, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-272-5690.
Docket No. 81N-0301 Federal Register 6/4/82 p. 24278

Enforcement Policy; Infant Formula Recalls FR

FDA is amending its enforcement policy regulations to add recall requirements for infant formula. The regulations, established in accordance with the Infant Formula Act of 1980, specify recall procedures to be used by manufacturers in removing from the marketplace an infant formula that does not provide the nutrients required by the Federal Food, Drug, and Cosmetic Act or that is otherwise adulterated or misbranded within the meaning of the Act. **Effective June 1, 1982.** For further information contact: John M. Taylor, Bureau of Foods (HFF-310), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3092.
Docket No. 81N-0053 Federal Register 4/30/82 p. 18832

Foods

Infant Formula Quality Control Procedures FR

FDA is establishing quality control procedures for the manufacture of infant formulas. The purpose of these procedures is to assure that the infant formulas contain the necessary nutrients at the specified levels as required by the Infant Formula Act of 1980. The final rule requires each manufacturer to establish a quality control system, but permits each manufacturer to adopt the system that is best suited to its needs. It permits manufacturers to analyze nutrients either during processing or after processing, but before the finished product is released by the manufacturer. **Effective July 19, 1982.** For further information contact: F. Edward Scarbrough, Bureau of Foods (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3117.
Docket No. 80N-0025 Federal Register 4/20/82 p. 17016

Canned Mushrooms; Standards of Identity and Fill on Container PR

FDA is proposing to amend the standard of identity for canned mushrooms based on consideration of the Recommended International Standard for Canned Mushrooms developed by the Codex Alimentarius Commission. FDA is also proposing to amend the standard of fill of container based on consideration of a petition by the National Food Processors Association (NFPA) and the Recommended International Standard for Canned Mushrooms. This action would promote honesty and fair dealing in the interest of consumers and would facilitate international trade. The Agency is also proposing a conforming amendment in the food additive regulation on calcium disodium ethylenediaminetetraacetate. **Written comments by August 23, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD. For further information contact: F. Leo Kauffman, Bureau of Foods (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1164.
Docket No. 81N-0049 Federal Register 6/22/82 p. 26843

Aflatoxins in Cottonseed Meal; Revised Action Level N

FDA is announcing a revised action level of 300 parts per billion (ppb) for aflatoxins in cottonseed meal intended for use as an animal feed ingredient for beef cattle, swine, and poultry. The revised action level is a result of an FDA evaluation of its overall policy for regulating aflatoxin contamination of feedstuffs for food-producing animals. Although the total evaluation is not completed, it has progressed to the point where FDA has determined that a change in the action level from 20 ppb to 300 ppb is needed to support, from a food safety point of view, the regulatory control of aflatoxin-contaminated cottonseed meal. Severe aflatoxin contamination of the 1981 cotton crop in the southwestern United States has led the Agency to establish this action level. This notice is being issued to inform interested persons of FDA's decision on this matter, to advise such persons of the availability of material the Agency has relied upon in establishing this action level, and to provide the opportunity to comment on the action level. **Written comments by September 28, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: John R. Wessel, Office of Regulatory Affairs (HFC-6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1815.
Docket No. 82N-0172. Federal Register 7/30/82, p. 00000

Medical Devices

Delegations of Authority and Organization; Medical Devices FR

FDA is amending the regulations for delegations of authority regarding medical devices. Bureau of Radiological Health officials are being delegated additional authority in the approval process for radiation-emitting medical devices. Bureau of Biologics officials are being delegated authority over medical devices which also are biologics or are used in the production of biologics. The new delegations will provide greater operating flexibility, more effective and efficient operations, and more expeditious handling of submissions from regulated industry. **Effective June 1, 1982.** For further information contact: Robert L. Miller, Office of Management and Operations (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

Docket No. 82-14723 Federal Register 6/1/82 p. 23705

Menstrual Tampons; User Labeling FR

FDA is issuing a final rule to require manufacturers of menstrual tampons to include information on toxic shock syndrome (TSS) in the labeling of the device. TSS is a rare, but serious and sometimes fatal, disease associated with tampon use. FDA is requiring that menstrual tampon packages contain a brief statement alerting consumers to the dangers of TSS and advising them to read and save information about TSS included in a package insert. If the TSS information itself is placed on the package, no alert statement is required. The language of the alert statement is specified, but tampon manufacturers may develop the information about TSS within guidelines specified in the final rule. **Effective Date:** The regulation will take effect for packages of tampons initially introduced or initially delivered for introduction into commerce on or after **December 20, 1982.** For further information contact: Maria Donawa, Bureau of Medical Devices (HFK-300), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7175.

Docket No. 80N-0425 Federal Register 6/22/82 p. 26982

Orthopedic Devices; General Provisions and Classification of 77 Devices PR

FDA is proposing general rules applicable to the classification of orthopedic devices in commercial distribution. The Medical Device Amendments of 1976 require the Agency to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble, FDA describes the development of the proposed regulation classifying 77 orthopedic devices. The preamble also describes the activities of the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel (formerly the Orthopedic Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of orthopedic devices. **Comments by October 1, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: James G. Dillon, Bureau of Medical Devices (HFK-410), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

Docket No. 78N-2830 Federal Register 7/2/82 p. 29052

General

Potassium Iodide As A Thyroid-Blocking Agent in a Radiation Emergency **NA**

FDA announces the availability of final recommendations about administering potassium iodide to the general public in a radiation emergency. The final recommendations prepared by FDA's Bureau of Radiological Health and the Bureau of Drugs are being made available to assist State and local authorities in developing emergency-response plans for preventing adverse effects from exposure to radiation in the event that radioactivity is accidentally released into the environment. The final recommendations are on display in, and comments may be submitted to, the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857: and copies for further information may be obtained from Bernard Shleien, Bureau of Radiological Health (HFX-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6220 or Edwin V. Dutra, Jr., Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.
Docket No. 81N-0087 Federal Register 6/29/82 p. 28158

Exemption of Antibiotic Drug and Antibiotic Susceptibility Medical Devices From Certification **PR**

FDA is proposing to amend the antibiotic drug and new animal drug regulations to exempt all classes of antibiotic drugs from batch certification requirements. FDA is also proposing to exempt antibiotic susceptibility devices from batch certification. Because of the high level of manufacturer compliance with existing standards, FDA has tentatively determined that batch-by-batch testing by FDA is not necessary to ensure the safety and efficacy of antibiotic drugs and antibiotic susceptibility devices. Under the exemption, manufacturers would not be required to obtain, before marketing, certification of each batch of antibiotic drug. In the Federal Register of May 11, 1982, FDA will announce an interim policy of discretionary replication of manufacturer's tests to avoid interruption of supplies of antibiotic drug products pending its final decision on this proposal. For further information contact: For human drugs: Robert J. Meyer, Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220. For animal drugs: Frank G. Pugliese, Bureau of Veterinary Medicine (HFV-103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442. For medical devices: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.
Docket No. 82N-0033 Federal Register 5/7/82 p. 19954

Antibiotic Drugs and Antibiotic Susceptibility Medical Devices **N**

FDA is announcing an interim policy of discretionary replication of manufacturer's tests of batches of antibiotic drugs and antibiotic susceptibility devices. The purpose of the interim policy is to avoid interruption of supplies of antibiotic drug products pending its final decision on the proposed rule to exempt these products from certification published in the Federal Register of May 7, 1982 (47 FR 19954). **Effective May 11, 1982.** For further information contact: For human drugs: Robert J. Meyer, Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220. For animal drugs: Frank G. Pugliese, Bureau of Veterinary Medicine (HFV-103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442. For medical devices: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.
Docket No. 82N-0150 Federal Register 5/11/82 p. 20186

*U.S. GOVERNMENT PRINTING OFFICE: 1982 384-692/1199 1-3

Go Ahead, Ask Your Doctor

You've just been handed a prescription. You start to look forward to better health. But what do you know about that drug? Do you understand what it is meant to do? Do you know how to take it? Medicines can have some side effects, and they have to be taken correctly. So, be sure to read instructions carefully, and don't hesitate to ask your doctor about:

- **When to take the medicine.** Some drugs should be taken on full stomachs, some on empty stomachs, some in the morning, some before going to bed.

- **How to take the medicine and how much.** With water, with milk or without anything? Should the dose be one or two spoonfuls or what?

- **What not to take with the medicine.** Some medicines don't mix with alcohol, others shouldn't be mixed with other drugs.

- **What side effects the drugs can cause.** Medicines may produce a variety of other reactions. Not all people will have the same side effects but you should know what the possibilities are.

There are many sources of information about prescription drugs. Ask your doctor or pharmacist.

A message from the Food and Drug Administration. For more material about being an informed patient, write to: FDA, HFE-88, Rockville, Md. 20857.

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Food and Drug Administration
Parklawn Bldg., 5600 Fishers Lane
Rockville, Maryland 20857

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FDA Consumer Update

April 1982

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Office of Consumer Affairs (HFE-20)
5600 Fishers Lane
Rockville, Maryland 20857

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Dear Consumer:

The primary objective of the Consumer Update is to alert consumers to the many opportunities that are available for participation in the workings of the Food and Drug Administration and in the regulatory process itself. If you do not have, and would like to receive, information on how to comment on proposed regulations, petition the FDA, or obtain Agency documents, please let us know.

I hope that you were able to take part in some of the activities scheduled for National Consumers Week (see page 4).

FDA has initiated a Committee on Patient Education (p. 1) with the dual purpose of coordinating the government's efforts to educate consumers about prescription drugs and to serve as a catalyst for private sector initiatives in this area.

On April 2, FDA published in the Federal Register an advance notice proposing a new policy to assure the safe use of food and color additives that contain small amounts of carcinogenic chemicals (see page 27). The Agency is soliciting your comments; they are due by July 1, 1982.

There are two tear-out pages in this issue. The first (p. 7) is a Consumer Interest Survey Form. If you have not yet completed one, you must do so if you wish to continue to receive the Consumer Update and other FDA information. The second (p. 11) is a reporting form for adverse reactions caused by medical devices. A list of types of devices can be found on page 10.

I would appreciate receiving your ideas on how we can make this publication more useful to you. Please contact me at the Office of Consumer Affairs (HFE-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone 301-443-5006 or TTY (for the deaf) 301-443-1818.

Sincerely yours,

Alexander Grant

Alexander Grant
Associate Commissioner for
Consumer Affairs

Issues 18 & 19 are on microfiche

HE 20.4010/3:

FDA Consumer Update

Activities and Information

COMMITTEE ON PATIENT EDUCATION

The Committee on Patient Education (COPE) was appointed in January by Commissioner Hayes at the direction of Health and Human Services Secretary Schweiker. Its goals are twofold: to coordinate the government's efforts to educate consumers about prescription (Rx) drugs; and to serve as a catalyst for private sector initiatives in this area.

The first meeting was an executive session at which the nineteen Committee members agreed on the establishment of a Patient Education Resource Center within FDA to facilitate the exchange of information between parties interested in patient education. Subsequent meetings have focused on presentations by outside organizations.

On February 10 the pharmaceutical corporation Ciba-Geigy discussed with the Committee its plans to provide $1 million toward funding and staffing a consortium of parties interested in patient education. This consortium, to be known as the Joint Commission on Patient Education, will encourage health professionals to provide more information to patients about Rx drugs, and will encourage patients to seek more information about drug use. FDA has encouraged other organizations to participate in the activities of the Joint Commission. The first full Commission meeting is expected in late May.

On February 24 the United States Pharmacopeial (USP) Convention reported on its numerous Rx drug publications for patients. The USP is about to initiate several new programs as well. It plans to distribute its book on advice to patients through the Academy of Family Physicians and to develop material for distribution to home computers and cable television networks.

On March 12 the American Medical Association met with the Committee to describe its Patient Medication Instruction (PMI) leaflets which will be distributed to practicing physicians for delivery to patients when prescriptions are written. This program will include PMIs for 20 drugs by the fall of 1982, and for 200 drugs by 1984. FDA has offered to review their materials and assist them in other ways to help make their program a success.

On April 6 officials of the American Society of Hospital Pharmacists described the products they have developed to support pharmacists in their role of helping patients better understand prescription medications. These include a brochure, "Understanding Your Prescriptions"; Medication Teaching Manual, a guide for patient counseling; audio visual presentations; and Consumer Drug Digest, a new publication about prescription drugs specifically for consumers.

After a meeting with one of the Committee's working groups, the Healthy Mothers/Healthy Babies coalition agreed to coordinate the dissemination of the USP book to pregnant women. They and the National Institute on Aging will also disseminate to their constituents patient education materials being developed by FDA. FDA has written to over 100 professional, consumer, and trade organizations telling them about the Committee and soliciting their support and assistance.

UPDATE ON SODIUM

In April 1981, FDA launched a major sodium program designed to provide more information to consumers about sodium and to encourage the sale of more foods that are lower in sodium content.

The results of the program thus far indicate progress in working with industry to voluntarily lower and label the sodium content of foods and in providing information to consumers on sodium. Some companies are now also test marketing or exploring the possibility of marketing low sodium foods.

FDA estimates that a third to a half of all the processed foods it regulates will have sodium labeling by the end of 1982. This has become a possibility as a result of Agency meetings with food trade associations and individual companies. Among the companies who have or who intend to place sodium labeling on foods in 1982 are: General Foods, General Mills, Del Monte, Campbell Soups, Frito-Lay, Procter and Gamble, Quaker Oats, and Beatrice Foods.

The National Food Processors Association, a trade association representing approximately 600 processors of fruit, vegetables, meat, fish, and specialty products, passed a resolution on November 5, 1981 endorsing voluntary sodium labeling and encouraging its members to label sodium on appropriate product categories. The Association also petitioned FDA requesting certain amendments to the food labeling regulations to make possible more widespread industry participation in the voluntary program. The Agency provided an interim response to the petition in January 1982 listing the interim compliance criteria to be followed by industry. These criteria which will be in effect until revoked or until action is taken on the sodium proposal now under consideration, enable industry to provide sodium labeling information promptly to consumers.

FDA has met with consumer groups at the national and local levels to encourage their active participation in the sodium program. Consumers and consumer groups have been asked primarily to help publicize and distribute information on sodium to their constituents. One consumer group, Center for Science in the Public Interest, petitioned FDA to request that health notices be required on salt packages.

The Agency has used the media -- radio, television, newspapers, and magazines -- to educate and to inform the public of the role of sodium in the diet and its relationship to high blood pressure and health in general. FDA has produced and made available to the public two articles on sodium and three other sodium publications are also being distributed.

Over 9500 of these publications have been requested so far and the demand continues to grow. The following is a list of the publications:

"Salt Shakes Up Some of Us" - FDA publication No. 80-2129

"The Case for Moderating Sodium Consumption" - FDA Publication No. 82-2158

"Sodium Sense"

"Straight Talk About Salt"

"The Sodium Content of Your Food"

In addition to requests for publications and information on sodium, FDA has received many letters from the public recommending that the amount of sodium in processed foods should be limited and that the sodium content of these foods should appear on the label.

FDA Commissioner Arthur Hull Hayes, Jr., M.D., has said that he will evaluate the results of the sodium program late in the year to determine whether additional action is needed.

SALMON RECALLS CONTINUE

What began in February with the initial recall from the market of 7-3/4 ounce canned salmon from one Alaskan cannery has continued into April with recalls now involving a total of eight packing plants and 50 million cans. Recalls now include 7-3/4 ounce cans of salmon packed in 1980 and 1981 by the following Alaskan firms: NEFCO-Fidalgo Packing Company, Chugach Alaska Fisheries, Diamond E. Fisheries, Wards Cove Packing Company, St. Elias Ocean Products Company, Whitney-Fidalgo Seafood Company, and Petersburg Fisheries.

The February recall was precipitated by the death of a Belgian man and the illness of his wife from botulism traced to the salmon packed by NEFCO-Fidalgo. Subsequent recalls followed an FDA investigation of cans from these packers. FDA believes a machine that shapes the cans may have torn some of their edges leaving holes or other defects in the seams when their ends were attached. The openings permit the possible formation of botulin, a toxin that can cause the often fatal disease botulism.

Since many salmon canneries use the same machinery, FDA reached an agreement with the salmon canning industry to call for all canners using the suspect machinery to inspect their cans in warehouses and recall any possibly defective cans. The Agency is also working with the National Food Processors Association and the can manufacturer to determine what action is needed to prevent the recurrence of such problems. (If defective lots of salmon continue to be found, public announcements will be made about their recalls, along with appropriate code numbers.) The industry advises consumers that only 7-3/4 ounce salmon cans are affected. They can be returned to the place of purchase if an obvious defect is found in the cans or if a consumer is unsure of the safety of the product. Visual examination of the can or the salmon cannot detect the presence of botulinum toxin.

GOOD READERSHIP RESPONSE TO CAFFEINE ARTICLE

In the April 1981 issue of Consumer Update, the Office of Consumer Affairs (OCA) included information on caffeine: a reproduction of a brochure entitled "Caffeine and Pregnancy", and a request to have the brochure distributed as widely as possible to pregnant women or to those planning on becoming pregnant.

The response to this request was dramatic. Between May and October 1981, OCA received requests for almost 25,000 brochures from physicians, hospitals, clinics, consumers, consumer groups, USDA Cooperative Extension offices, industry, and educational institutions.

Examples of how the brochure was distributed or advertised included Dr. Jean Mayer's syndicated nutrition column, the American College of Obstetricians and Gynecologists' newsletter, supermarket publications, direct mailings, newsletters of other organizations, news releases for radio and newspapers, and posting on bulletin boards.

PRESIDENT PROCLAIMS NATIONAL CONSUMERS WEEK

In proclaiming the week of April 25-May 1 as National Consumers Week (see page 5), President Reagan set the tone for an activity-filled week highlighting the importance of lifelong consumer education. The goal of National Consumers Week was to focus national attention on consumers as the center of economic activity, to call attention to the importance of lifelong consumer education; and to promote greater understanding of the systems, principles, institutions, and government as they relate to our ability to improve the quality of our lives.

The U.S. Office of Consumer Affairs (USOCA) coordinated the week's activities together with representatives of other federal agencies, state and local government agencies, consumer organizations, industry, and the media.

FDA activities for National Consumers Week were coordinated by Alexander Grant, Associate Commissioner for Consumer Affairs, who, as co-chairperson of the Human Resources Task Force, is the Agency's liaison with USOCA.

FDA promoted consumer-oriented events and activities primarily at the local level and in cooperation with other agencies and offices. FDA's consumer affairs officers were asked to focus their activities on two Agency consumer issues of high priority -- patient drug information and sodium education -- as well as on issues of specific interest in the various FDA districts.

At the national level, a consumer stamp issued by the Post Office on April 25 was tied into a White House ceremony on April 27. During the week a media fair for school teachers was held and consumer exhibits were featured. Also planned were media programs, public service announcements, a conference sponsored by the Committee on Employment of the Handicapped, and a Howard University conference featuring Esther Peterson and Averill Harriman.

Proclamation 4892 of January 21, 1982

National Consumers' Week

By the President of the United States of America

A Proclamation

An informed and educated consumer is vital to the long-term healthy growth of our economic system. Consumer education can help us make decisions that are right for ourselves and right for our economy. It helps motivate young people to formulate more realistic, attainable standards for a higher quality of life. It helps adults solve problems and make decisions in our increasingly complex financial world. And because consumer education promotes responsible consumer behavior and customer satisfaction, it is beneficial for consumers, business and government.

The American enterprise system has given us the greatest and most diverse outpouring of goods and services of any economy in history. We are the most prosperous nation in the world with unequaled opportunities for individuals to enjoy the fruits of their labors. Honest transactions in a free market between buyers and sellers are at the core of individual, community, and national economic growth.

In the final analysis, an effective and efficient system of commerce depends on an informed and educated public. Consumer dollars shape the marketplace with an expenditure of roughly two-thirds of the gross national product—almost twice that of government and business combined. The strength of this consumer purchasing power carries with it a responsibility that each citizen wisely decide which economic resources are to be saved and which are to be spent where.

There is a proper role for government involvement in the marketplace. For example, it is the responsibility of government to insure that our food and drug supplies are safe and that defrauders are brought to justice. Too much government regulation, however, simply adds to the costs to business and consumers alike without commensurate benefits. We are striving to correct excesses, at the same time recognizing that informed and educated consumers are our best hope for prosperity, efficiency, and integrity in the marketplace.

As we enter a new era of greater economic freedom, I urge schools, community organizations, the media, labor unions and businesses to develop programs and information so that consumer and economic education and information will be readily available to all.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby designate the week beginning April 25, 1982, as National Consumers' Week.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-first day of January, in the year of our Lord nineteen hundred and eighty-two, and of the Independence of the United States of America the two hundred and sixth.

Ronald Reagan

TIMOLOL

On November 25, 1981 Commissioner Arthur Hull Hayes, Jr., M.D., announced FDA approval of timolol, the first drug to be specifically labeled for use in preventing death and further heart attack for a high risk group of people -- those who have just survived an initial heart attack.

The approval of the drug was based on a major three-year Norwegian study which found that when people were given timolol in the first weeks and months after an initial heart attack, their risk of death and a second non-fatal heart attack was significantly reduced -- by about one-third.

Timolol belongs to a class of drugs known as beta-blockers, five of which are approved and used in the United States for other medical indications. Other beta-blockers -- propanolol and metopropol -- are being studied for use in treating heart disease. According to Dr. Hayes, with timolol and other similar drugs that may have the same effect, we are entering a new era in the treatment of heart disease, the nation's number one killer. These drugs will hopefully prolong the lives of thousands of Americans each year.

Dr. Hayes added a personal footnote to the announcement, speaking not only as the FDA Commissioner, but also as a cardiologist who has spent a major part of his professional life treating patients with heart disease and high blood pressure. He said he has witnessed, during the course of his own lifetime, the development of major drugs to treat diseases that once killed thousands and even millions of people. In the cardiovascular area, he cited a number of factors that affect our heart disease rate. For example:

- greater awareness of the relationship between diet and health;
- emphasis on the importance of controlling body weight and getting proper exercise;
- more recognition of the relationship between smoking and health;
- attention to high blood pressure and the relationship between sodium and high blood pressure;
- the development of new drugs to treat heart disease.

Although the relative importance of these positive changes on the rate of heart disease is not known, there has been a decrease in the death rate from this disease since 1968.

Dr. Hayes concluded, "As we enter a new era of cardiovascular protection through use of beta-blockers, and as we educate more people about what they can do to protect themselves -- such as controlling their weight, watching their diets, and getting more exercise -- I look forward to a continued decline in cardiovascular deaths."

CONSUMER INTEREST SURVEY FORM

During the past year, the Office of Consumer Affairs (OCA) has sent Consumer Interest Survey Forms to addressees on the OCA mailing lists. Data from returned forms have been entered into the computer; these names and addresses will be used for all future mailings of OCA information. If you have not completed a Consumer Interest Survey Form and wish to continue to receive the Consumer Update, you must complete and return the survey form on page 7. This is the last time the old mailing lists will be used. (If you have completed and submitted a survey form, disregard this request.)

April 1982 *Activities & Information*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

CONSUMER INTEREST SURVEY

NOTE: The Office of Consumer Affairs is updating and computerizing its consumer information mailing list for greater flexibility and speed in reaching you.

INSTRUCTIONS

1. Please complete this form and return it as soon as possible if you wish to continue receiving consumer information. If not, your name will be deleted from our mailing list.
2. Fold and seal the form as indicated to show our mailing address only.
3. Print or type all entries.

NAME AND ADDRESS OF CONSUMER

1. NAME *Last* *First* *Middle Initial*
2. NAME OF ORGANIZATION
3. STREET ADDRESS
4. CITY STATE ZIP CODE

5. **PRIMARY AFFILIATION** *(Check one)*

- ☐ (A) COMMUNITY ORGANIZATION
- ☐ (B) CONSUMER ORGANIZATION
- ☐ (C) HEALTH INTEREST GROUP
- ☐ (D) CITY/COUNTY/STATE/FEDERAL CONSUMER AGENCY
- ☐ (E) EDUCATOR/CONSUMER EDUCATOR
- ☐ (F) INDIVIDUAL CONSUMER
- ☐ (G) HISPANIC ORGANIZATION
- ☐ (H) HEALTH PROFESSIONAL
- ☐ (I) INDUSTRY CONSUMER
- ☐ (J) WOMEN'S ORGANIZATION
- ☐ (K) HANDICAPPED
- ☐ (L) AGED

6. **AREA OF INTEREST** *(Check as many as applicable)*

- ☐ (FO) FOOD SAFETY *(additives, coloring, preservatives)*
- ☐ (CO) COSMETICS
- ☐ (HD) HUMAN DRUGS *(including drug abuse treatment)*
- ☐ (AD) ANIMAL DRUGS AND FEEDS
- ☐ (MD) MEDICAL DEVICES *(including implanted devices and diagnostic products)*
- ☐ (BI) BIOLOGICS *(blood products, vaccines, etc.)*
- ☐ (RH) RADIOLOGICAL HEALTH *(electronic products, x-rays, ultrasonic devices, etc.)*
- ☐ (GI) GENERAL CONSUMER INFORMATION

7. COMMENTS

FORM FDA 3183 (7/80) SEAL & FORWARD

WEIGHT CONTROL DRUG PRODUCTS

In the February 26, 1982 issue of the Federal Register, FDA published for public comment an advisory panel's report calling two ingredients in over-the-counter diet aids, benzocaine and phenylpropanolamine, safe and effective in weight control.

In a preamble to the panel report, however, FDA noted that reports published in the medical literature after the panel report was submitted indicate that phenylpropanolamine doses higher than those currently marketed (but within the range recommended as safe by the panel) cause elevation of blood pressure. Other studies, reviewed by the panel, showed no such effect at currently marketed dosages. FDA called for more research to determine a safe dose range for phenylpropanolamine and the extent to which the ingredient induces or aggravates high blood pressure.

Until this is accomplished, FDA will permit phenylpropanolamine to be used at current levels for which there is a history of use in weight control but will not permit the higher dose diet aids as recommended by the panel and available abroad. Traditional U.S. levels total 75 milligrams or less per day. The panel said doses of up to 150 milligrams would be safe.

The panel found none of the other 111 ingredients in nonprescription diet pills had been proven effective. Benzocaine is an anesthetic which works by numbing the taste buds, and is used in lozenges, candy and gum.

The panel said phenylpropanolamine and benzocaine might help reduce a dieter's appetite, but cannot themselves cause weight loss; only a reduction in calories consumed, or an increase in exercise to burn off excess calories, can cause someone to lose weight.

After comments are evaluated, FDA will propose a regulation establishing, for the first time, standards for the ingredients and labeling of these products. Any product that fails to meet the standards finally adopted will face removal from the market. The comment period ends May 27, 1982. (See page 25).

OFFICIAL BUSINESS
PENALTY FOR PRIVATE
USE. $300

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

BUSINESS REPLY MAIL
FIRST CLASS PERMIT NO. 946 ROCKVILLE, MD.
POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

Associate Commissioner For Consumer Affairs
Food And Drug Administration *(HFE-50)*
5600 Fishers Lane, Room 16-85
Rockville, MD 20857

MEDICAL DEVICE PROBLEM REPORTING PROGRAM (PRP)

The Food and Drug Administration is responsible for enforcing the Federal Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976.

Medical devices include a wide variety of products. A medical device is any product which can be used to diagnose, treat, cure, or relieve adverse conditions or prevent disease or other medical conditions. It can be used to: monitor a disease (a dip stick to test for the presence of glucose in blood or urine); treat a disease (a syringe to deliver insulin); affect body structure (a prosthesis); affect body function (a pacemaker); or offer protection (a bandage). Unlike a drug, a medical device does not rely on chemical or metabolic interaction in or on the user's body to accomplish its purpose. A list of medical devices, of which consumers may have first-hand knowledge, is found on page 10.

As with any product, problems can occur. A device may have a defective part and not function properly; it may be labeled "Sterile" but have a torn package; it may cause an adverse reaction; its labeling may contain confusing instructions; or the labeling may make claims for performance which the product does not fulfill.

The PRP is the program currently available to 224,000 health care professionals and engineers to report problems with medical devices. It is funded by FDA and managed by the United States Pharmacopeial (USP) Convention, Inc. Reports are entered into the Device Experience Network (DEN), the data base where reports are stored. Each report is evaluated and the potential of the device to cause a serious problem is assessed. Based on the findings, FDA may conduct a follow-up visit to the manufacturer to determine why the problem occurred and what steps the manufacturer took to correct the problem.

Because the user of a medical device is a good source of information about its performance, FDA is expanding the reporting program to include consumers. If you have, or have had, a problem with any type of medical device, the Food and Drug Administration would like to know about it.

There are several methods that you can use to report problems:

- complete the reporting form with self-mailer on page 11 of this issue of the Update.
- call the medical device complaint coordinator at the FDA office nearest you (cities and phone numbers are listed on page 15);
- call toll-free 800-638-6725 from 8:00 a.m. to 4:00 p.m. EST (the USP).
- describe the problem on a plain sheet of paper, use the code number 27 (identifies it as a consumer report), and mail to USP, 12601 Twinbrook Parkway, Rockville, MD 20852, Attention: Dr. Joseph G. Valentino.

Adverse reaction reports have resulted in substantive corrective actions. The following are some examples:

- A user noted that bottles of water for inhalation therapy had a different expiration date than that stated on the carton. Investigation showed that damage had occurred to the external carton and the manufacturer had transferred the contents to another carton without correcting the expiration date on the outer carton.
- A urine test kit contained the incorrect color chart. The firm recalled the product.
- A user reported that she could not draw insulin into the syringe. It was found to be plugged with silicone, used to lubricate the needle.
- In another problem with a syringe, the plunger was sticking to the barrel, making it difficult to withdraw and expel the medication. The firm redesigned the syringe for easier manipulation.

DEVICES WITH MEDICAL CLAIMS OR RADIATION EMITTING (R-E) PRODUCTS

braces, orthopedic
contact lenses, hard, soft, and all accessories
contraceptives (condoms, diaphragms, IUDs)
dentures (cleaners, resins, repair kits, pads and liners)
dialyzers for home use
diathermy equipment (R-E)
electrical muscle stimulators
eyeglasses and frames
hearing aids
laser shows (R-E)
liquid crystal temperature strips
monitors for: apnea
blood pressure
heart rate
oxygen equipment (portable, home use)
pregnancy test kits (sold over the counter)
reagent strips/tablets (to test urine or blood for glucose, ketones, etc.)
sanitary napkins; tampons
sun lamps (R-E)
syringes (insulin)
thermometers (oral and rectal)
traction devices
ultrasound devices (R-E)
vaporizers
wheelchairs (powered, special grade, stand-up, stair-climbing)

Form Approved, OMB No. 57-R0059

MEDICAL DEVICE AND LABORATORY PRODUCT
PROBLEM REPORTING PROGRAM

27

ACCESS

DATE

1 TRADE NAME AND TYPE OF PRODUCT *(Attach labeling, if available)*

2 PRODUCT IDENTIFICATION
LOT NO SERIAL NO PRODUCT NO

3 NAME AND ADDRESS OF MANUFACTURER

4 EXPIRATION DATE *(If applicable)*

5 YOUR NAME

6 YOUR FACILITY S NAME ADDRESS AND ZIP CODE

AREA CODE AND PHONE NUMBER OF YOUR FACILITY

7 PROBLEMS NOTED OR SUSPECTED

RETURN TO
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852
Attention: Dr. Joseph G. Valentino

OR

CALL TOLL FREE ANYTIME
800-638-6725*
IN THE CONTINENTAL UNITED STATES
*In Maryland, call collect (301)881-0256 between 9:00 AM and 4:30 PM

INTRAOCULAR LENSES (IOL)

In December 1981, FDA granted its first approval of an intraocular lens (IOL) -- a plastic lens for surgical implantation after removal of the natural lens. IOLs have been used experimentally, primarily after cataract surgery, for many years. This approval, recommended by FDA's Ophthalmic Devices Section, an expert advisory panel which includes ophthalmologists and optometrists, marks the first time FDA has determined that a particular brand and style of lens is safe and effective.

The approved lens, manufactured by Coburn Optical Systems of Clearwater, Florida, is an anterior chamber lens, one of four classes of IOLs. It is implanted in the anterior chamber in front of the iris, the colored part of the eye. The lens is labeled for use in patients 60 years of age or older, based on tests done with patients in this age group.

FDA Commissioner Hayes said, "This approval marks a major milestone in the clinical history of intraocular lenses. It shows that the lenses can be an alternative to eyeglasses and contact lenses for some people whose natural lenses have been removed. They can be of particular help to elderly patients who cannot see well with glasses alone and who have difficulty handling contact lenses."

The Agency is reviewing data from other lens manufacturers and more applications are expected to be submitted. If the data adequately demonstrate the benefits of these other brands and styles, FDA will grant additional approvals.

To help collect data on possible long-term effects of the lenses, a tollfree telephone number has been established for physicians to report any significant complications. Patients who have a lens implanted will be given an identification card and registered with the company to help identify the lens if any problems arise.

Product Problem Reporting Program
12601 Twinbrook Parkway
Rockville, MD 20852

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES

BUSINESS REPLY MAIL
FIRST CLASS PERMIT NO. 40, ROCKVILLE, MD.

Postage will be paid by addressee:

DR. JOSEPH G. VALENTINO
The U.S. Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway
Rockville, Maryland 20852

INFANT APNEA MONITORS

Apnea is a condition in which an individual's respiration stops. In obstructive apnea, the patient tries but cannot breathe because the airways are blocked (e.g., by the tongue). In central apnea, a loss of neural control causes the patient to stop breathing.

Although uncommon, apnea is dangerous because it causes a reduction of the body's essential oxygen, possibly leading to irreversible brain damage or death. It is suspected in cases of Sudden Infant Death Syndrome (SIDS). High-risk infants must be watched or monitored constantly because the onset of apneic episodes is unpredictable.

Apnea monitors are designed to reduce the need for constant visual observation of infants at high risk of developing SIDS. The monitor has an alarm designed to sound if the infant stops breathing. Apnea monitors do not resuscitate the patient, so someone at the scene should be trained in cardiopulmonary resuscitation.

Problems exist with the use of infant apnea monitors. Since indirect apnea monitors record breathing efforts, not actual air flow, they may not detect obstructive apnea. Patient movement, cardiovascular function, or vibrations from nearby equipment can be misinterpreted as breathing, possibly resulting in the failure of the monitor to sound an alarm even though the baby has stopped breathing. Other risks associated with the use of apnea monitors include false alarms, power or equipment shortages or failures, inaccuracy of the controls, and errors in adjusting the controls or resetting the alarm.

FDA requested manufacturers of apnea monitors to review their products' performance and to let us know the results of the review and what steps will be taken to correct the problems. The Agency feels that apnea monitor labeling should reflect the need for careful use and monitoring of the equipment. FDA is interested in consumer experiences with apnea monitors and answers to questions such as:

- What make and model monitor did you use?
- Did you decide to monitor and choose the particular monitor based on a doctor's recommendation?
- Were you enrolled in a home-monitoring project group and did you receive any CPR training?
- What problems did you have with the device?
- What features did you like, and what features did you dislike or believe should be improved?

If you have any information on apnea monitors you feel would be of interest to FDA, you may submit it by one of the four methods listed in the page 9 article on Medical Device Problem Reporting.

ORAL CONTRACEPTIVE LABELING

On February 11, the Fertility and Maternal Health Drugs Advisory Committee met to begin review and discussion of the patient and physician labeling for oral contraceptives (OCs). Based on testimony presented to the committee by consumers, health professionals, and industry, the committee will recommend labeling revisions that will reduce complexity and add or modify information.

A number of national consumer organizations made presentations at the February meeting. They highlighted consumer concerns with current labeling and made recommendations including:

- State the risk associated with taking oral contraceptives, not only for women who smoke but also for women with a family history of various diseases, i.e., diabetes, thromboembolic disorders.
- Revise the present misleading statements claiming that other forms of birth control are less effective but carry fewer or no risks or require greater effort than taking the pill.
- Present a discussion of the risks of other forms of contraception as well as an explanation of the benefits of OC use, e.g., high effectiveness rate, minimization of various diseases such as pelvic inflammatory disease and rheumatoid arthritis.
- Specify the proper use of oral contraceptives before and after elective surgery.
- Revise the labeling to indicate that breastfeeding is not a contraindication for taking all types of OCs. While use of combination OCs can result in a decrease in the quantity of breast milk, this association has not been found with progestin-only pills.

The committee will meet again in May to consider recommendations to the Agency on labeling revisions. After a full FDA review, the proposed revised guidelines for oral contraceptive labeling will be published in the Federal Register for comment.

To receive information on oral contraceptive labeling or to make a presentation at the May meeting, please contact Dr. A. T. Gregoire, Executive Secretary of the Fertility and Maternal Health Advisory Committee at (301) 443-3490.

VACCINE FOR LIVER DISEASE

On November 16, 1981 FDA approved a new virus vaccine to combat Hepatitis B. To be manufactured by Merck Sharp and Dohme, it is the first new viral vaccine in ten years and the first vaccine made directly from human blood to be licensed in the United States. Due to lengthy production time, the vaccine will not be available for broad distribution until mid-1982.

Hepatitis B is considered a major public health problem in the United States with 200,000 to 300,000 new infections each year, 400,000 chronically infected carriers, and thousands who suffer from degenerative liver disease as a result of hepatitis B infection. The incidence of hepatitis B in some developing countries is much greater than in the United States, and it is estimated that up to 200 million hepatitis B carriers exist worldwide. The new vaccine has a potential then for a dramatic effect on the health of the people, not only in this country but in many other nations as well.

Recent research on the hepatitis B virus has suggested an association with liver cancer, the most common form of cancer worldwide, although accounting for only two percent of all cancers in this country. Studies show that patients with liver cancer are more likely to have had a chronic hepatitis B infection than the general population. Therefore, this vaccine may save people not only from liver disease but from one form of cancer as well.

Once the drug is available it will be recommended initially for those people at high risk of acquiring the disease, such as health care workers, drug addicts, and people with numerous sexual contacts.

FDA CONSUMER COMPLAINT COORDINATORS FOR MEDICAL DEVICES

FDA OFFICE	TELEPHONE	FDA OFFICE	TELEPHONE
Atlanta, GA	(404) 881-3218	Minneapolis, MN	(612) 725-2121
Baltimore, MD	(301) 962-3593	Nashville, TN	(615) 251-5851
Boston, MA	(617) 223-2266	New Orleans, LA	(504) 682-6344
Buffalo, NY	(518) 472-6043	New York, NY	(212) 965-5725
Chicago, IL	(312) 353-7840	Newark, NJ	(201) 645-6591
Cincinnati, OH	(513) 684-3505	Orlando, FL	(305) 855-0900
Dallas, TX	(214) 767-0312	Philadelphia, PA	(215) 597-4113
Denver, CO	(303) 837-4916	St. Louis, MO	(314) 425-4137
Detroit, MI	(313) 226-6260	San Francisco, CA	(408) 275-7548
Houston, TX	(713) 226-5581	San Juan, PR	(809) 753-4443
Kansas City, MO	(816) 374-5521	Seattle, WA	(206) 442-5319
Los Angeles, CA	(213) 688-3771	San Diego, CA	(714) 293-5168

PROPOSAL TO REVOKE THE PPI FINAL RULE

On February 19, 1982, FDA published in the Federal Register a proposal to revoke the final rule concerning Patient Package Insert (PPI) requirements for Prescription Drugs which was published in September 1980. It was a plan to test patient package inserts for ten drugs over a three-year period.

FDA still believes strongly that informing patients more fully about prescription drugs will significantly improve the quality of their health care. However, our review of the pilot program showed that it had significant limitations and that it imposed unreasonable constraints on the health care system. During our review, we learned that many physicians, pharmacists, and other health professionals believe there are more effective and cost-efficient ways to bring information to consumers. The Agency feels that the

goals of providing patients information can best be achieved by cooperating with health professionals and others to expand current initiatives in patient education. FDA sees its role as a catalyst for encouraging a wide variety of public and private sector initiatives that can provide consumers with more information than may have been possible under the more restrictive pilot program.

This proposal would not affect FDA's authority to require PPIs for specific drugs at a later date, nor would it revoke existing requirements for the distribution of PPIs with oral contraceptives, certain intrauterine devices, estrogens, and progestational drug products.

ALCOHOL, CAFFEINE, AND PREGNANCY

In 1980 Louis Harris and Associates conducted a multipurpose survey for FDA's Bureau of Foods. A section of the survey questioned 1499 "primary food shoppers" on their awareness of the possible hazards to pregnant women or to their unborn children of consumption of alcohol and caffeine. The shoppers were also asked to evaluate the seriousness of the problem and the need, if any, for Federal action to address the problem. The answers to these questions have been incorporated into a 1981 Bureau of Foods report entitled: "Alcohol, Caffeine, and Pregnancy: The Public View." Highlights of the report are listed as follows:

1. Awareness of the potential danger of consumption of alcohol and caffeine by pregnant women.

   - 86% reported having read or heard about hazards of alcohol.
   - 60% reported having read or heard about hazards of caffeine.
   - Reported awareness climbs with increasing levels of education and is higher among women of childbearing age and among parents of young children.
   - Only a minority remember any details of what they have read or heard.

2. Evaluation of the seriousness of the problem.

   - 80% consider fetal alcohol syndrome to be a serious problem.
   - 53% consider the potential effect of caffeine to be a serious problem.
   - Evaluation of the seriousness of both problems rises with increasing levels of education and is higher among women of childbearing age and among parents of young children.

3. Desire for Federal action to address the problem.

   - 33% of those who view alcohol consumption during pregnancy as a serious problem (or 27% of all respondents) urge Federal action; 67% are opposed.
   - 25% of those who view caffeine consumption during pregnancy as a serious problem (or 13% of all respondents) urge Federal action; 75% are opposed.
   - For both problems, the call for Federal action is highest among parents of very young (under age 5) children.
   - For alcohol, the Federal actions most frequently suggested were: mass-media public-information programming (5%), warning labeling (3%), and control of the manufacture of sale of alcoholic beverages (5%).

- For caffeine, the Federal actions most frequently suggested were mass-media public-information programming (3%) and warning labeling (3%).

From the results of the survey it appears that the message regarding the potential hazards of alcohol and caffeine to pregnant women and their unborn children is getting across.

Citizens Petitions

CSPI PETITION TO REQUIRE NOTICE ON SALT PACKAGES

On December 28, 1981, The Center for Science in the Public Interest (CSPI) petitioned the Food and Drug Administration to request the Commissioner to promulgate a regulation requiring that all packages of salt, table salt, iodized salt, iodized table salt, and sea salt, for human food use, having a net weight of 1/2 oz. or greater, intended for retail sale to consumers and shipped in interstate commerce, bear a health notice.

The petition cited the fact that FDA has begun a program to encourage industry to voluntarily reduce the sodium content of their products and to list the sodium content on the label, since the majority of sodium in a person's diet comes from processed foods. Because estimates of the proportion of sodium added in cooking or at the table range from 10-33 percent, the petitioner proposes that FDA require the following health notice on all packages of salt weighing more than 1/2 oz.

> The Surgeon General has determined that, for many people, a diet high in sodium or salt may produce high blood pressure. High blood pressure increases the risk of heart attack and stroke. The public is advised to limit salt consumption by cooking with only small amounts and refraining from adding salt to food at the table.

The petition suggested that packages of salt weighing less than 1/2 oz. could carry a briefer notice such as:

> "The Surgeon General has advised the public to eat less salt."

On Public Advisory Committees

CONSUMER VACANCIES ON FDA PUBLIC ADVISORY COMMITTEES

The Food and Drug Administration's Office of Consumer Affairs is seeking candidates for nomination to serve as consumer representatives on ten FDA Public Advisory Committees. The Agency receives advisory opinions from technical committees on prescription drugs, medical devices, biological products, toxicological research, medical radiation, and radiation safety standards. Most committee members are experts in their respective fields. To fill upcoming openings and to assure that the consumers' needs will be adequately addressed, FDA is seeking consumer candidates who are knowledgeable in the above fields and who can represent the public interest on these technical advisory committees. Consumer-nominated members for the Bureau of

Drugs committees are required to have technical/professional expertise since they are voting members.

The ten upcoming advisory committee vacancies for 1982 are as follows:

Bureau of Drugs: (see * for one example of a committee's function)

1. Anesthetic and Life Support Drugs Advisory Committee
2. Cardiovascular and Renal Drugs Advisory Committee
3. Oncology Drugs Advisory Committee
* 4. Psychopharmacologic Drugs Advisory Committee
evaluates psychoactive drug products that are used in the practice of psychiatry and stimulant drugs used to treat hyperactivity in children. Candidates interested in this committee should possess technical background in such fields as adult and pediatric psychiatry, neurology, psychopharmacology, psychology, behavioral research, and biostatistics.

Bureau of Medical Devices: (see ** for one example of a panel's function)

1. Hematology Section
2. Circulatory Systems Devices Panel
3. Dental Section
4. General Hospital and Personal Use Section
** 5. Immunology and Microbiology Devices Panel
reviews premarket approval application information for medical devices used in the immunology field, such as tumor-asociated antigens for the detection of cancer, and cell-surface antigens for the detection of viral diseases. Consumer representative candidates for this vacancy should have an expressed interest in consumer affairs along with technical understanding of the biomedical sciences.

National Center for Toxicological Research

1. National Center for Toxicological Research Advisory Committee

For all FDA Public Advisory Committees we are seeking candidates who are aware of the consumer impact on committee issues, and also possess enough technical background to understand and actively participate in the committee's work. For example, FDA will consider candidates who possess the ability to analyze data, understand research design, discuss benefits versus risks, and evaluate the safety and efficacy of the products under committee review.

The next selection of consumer members is scheduled to take place in June 1982. A consortium of nine consumer organizations which screens and interviews candidates for the above openings will make recommendations to Agency and Department officials who will then make the final selections. After clearance for conflict of interest, chosen candidates are appointed as special government employees. They are paid travel and lodging expenses plus $128.80 per day for attending an average of four two-day meetings a year.

Organizations with nominees and individual applicants interested in serving as consumer representatives should contact Naomi Kulakow, Director, Policy Formulation Staff, FDA Office of Consumer Affairs (HFE-40), 5600 Fishers Lane, Rockville, MD 20857, 301-443-5006.

PROFILES OF CONSUMER MEMBERS ON FDA ADVISORY COMMITTEES

FDA advisory committees are composed of panels of outside experts who consider issues related to the approval or disapproval for marketing of drug, medical device, radiological, and biological products. Offering a unique combination of scientific/technical expertise and consumer credentials to committee deliberations, consumer members serve on 35 FDA advisory committees.

To encourage direct interaction between the public and the consumer advisory committee members, in this issue of the Consumer Update we are initiating a series of profiles on consumer members and the work of their committees.

Cardiovascular and Renal Drugs Advisory Committee

As the name implies, this committee considers complex questions on certain drugs for the cardiovascular and renal (kidney) systems. Since 1980, Thomas Reinders has served as the consumer-nominated member of the committee. With a Doctorate in Pharmacy and extensive teaching experience, he is highly qualified to offer the committee sound advice, particularly on pharmacological effects of drugs.

Closely involved with the consumer community, Dr. Reinders speaks to state and local groups on the use of prescription and over-the-counter medications. He also worked with the American Society of Hospital Pharmacists which developed a patient education teaching manual containing consumer information on 150 major types of medication.

As a consumer-nominated member, Dr. Reinders considered questions of safety, efficacy, and labeling on two recently-approved new drugs -- nifedipine and timolol. Nifedipine, a calcium channel blocker, can be used to treat angina pectoris (chest pain associated with heart disease in which the arteries that feed the heart become blocked and cannot provide an adequate blood supply). Timolol, a beta blocker available in tablet form, is specifically labeled for use in preventing death and further heart attacks among people who have just survived an initial heart attack.

Consumer issues relating to drugs used to treat the cardiovascular or renal systems, may be communicated to Dr. Reinders at the following address:

Thomas Reinders, Pharm. D.
Medical College of Virginia
Box 581 MCV Station
Richmond, Virginia 23298
804-786-7095

Obstetrics - Gynecology (Ob-Gyn) Advisory Panel

This advisory panel reviews premarket approval applications for medical devices used in the field of obstetrics and gynecology, such as intrauterine devices (IUDs) and tampon products. When information became available on the possible relationship between tampon use and Toxic Shock Syndrome (TSS), the panel recommended various actions to the Agency.

Joan Graff, an attorney who serves on the panel as a consumer representative, contributed significantly to the development of these recommendations:

- Menstrual tampons should be reclassified from Class II to Class III, the most stringent category.
- A patient package insert (PPI) should be formulated for menstrual tampons.
- FDA should continue its intensive campaign to alert women, physicians, and other health professionals about TSS.
- Further studies to clarify the etiology of TSS and its association with tampons should be reviewed by an expert group familiar with the pertinent health issues.

Ms. Graff is interested in discussing consumer concerns related to Ob-Gyn medical devices with individuals and groups in order to develop a stronger consumer network. She works with the California Coalition for the Medical Rights of Women on women's health issues and can be reached at the following address:

Ms. Joan Graff
Legal Aid Society of San Francisco
Employment Law Center
693 Mission St., 7th Floor
San Francisco, California 94105
415-495-6420

NEW DRUG APPROVALS

The Food and Drug Administration approved 27 "totally new" drugs in 1981 -- the most new chemicals approved in one year for use as drugs since the passage of the 1962 legislation governing drug approval. The total is more than twice the 12 approved in 1980.

According to FDA Commissioner Hayes, two drugs in particular represent important therapeutic gains. Alprostadil can temporarily treat infants with congenital heart defects prior to surgery, and ketoconazole can treat internal fungus diseases.

Other new drugs are verapamil and nifedipine, heart drugs known as calcium blockers; captopril, for stubborn cases of high blood pressure; albuterol, for asthma; sucralfate, for ulcers; and several antibiotics.

The approval of these new drugs is an important step in the Agency's goal to reform the drug approval process. Speeding the review of lifesaving new drugs will allow the public to benefit from medical advances without needless delay.

DRUG INFORMATION AVAILABLE FROM USP

"About Your Medicines" is the bimonthly consumer newsletter of the U. S. Pharmacopeial Convention, a non-profit organization of health professionals working together in the public interest. The objective of the newsletter is to provide the consumer with timely information on drugs and drug use. Subscriptions are available at $5.00 per year (Maryland residents add 5% sales tax) from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

District Consumer Exchange Meetings

District

New Orleans, LA
When: May 6, 1982, 2:00 p.m.
Where: Lafayette, Louisiana: Chamber of Commerce Building, 804 East St. Mary Boulevard
Contact: Frances G. Brysson, Consumer Affairs Officer, 504-589-2420

New Orleans, LA
When: May 7, 1982, 10:00 a.m.
Where: Lake Charles, Louisiana: McNeese University, Ryan St., Gayle Hall Auditorium
Contact: Frances G. Brysson, Consumer Affairs Officer, 504-589-2420

San Francisco, CA
When: May 11, 1982, 1:00 p.m.
Where: Honolulu, Hawaii: Federal Office Building, Rm. 6323, Ala Moana and Punchbowl
Contact: Karen K. Erdman, Consumer Affairs Officer, San Francisco, 415-556-2062; Robert Howell, Resident in Charge, Honolulu, 808-546-8387

Baltimore, MD
When: May 17, 1982, 2:00 p.m.
Where: Morgantown, West Virginia: Monongalia County Health Department, 453 Van Voorhis Road
Contact: Anne B. Lane, Consumer Affairs Officer, 301-962-3731

Cincinnati, OH
When: June 9, 1982, 1:00 p.m.
Where: Dayton, Ohio: Room 504, The Federal Building, 200 West Second Street
Contact: Ruth Weisheit, Consumer Affairs Officer, 216-522-4844

Cincinnati, OH
When: June 10, 1982, 1:30 p.m.
Where: Cleveland, Ohio: Room 5525A, Federal Building, 550 Main Street
Contact: Ruth Weisheit, Consumer Affairs Officer, 216-522-4844

Philadelphia, PA
When: June 16, 1982, 1:00 p.m.
Where: Philadelphia, Pennsylvania: William H. Green Federal Building, Room 7306, 6th and Arch Streets
Contact: Theresa A. Young, Consumer Affairs Technician, 215-597-0337

Directory

LOCATIONS WITH CONSUMER AFFAIRS OFFICERS

Atlanta, GA 30309
1182 W. Peachtree Street, N.W.
Phone: (404) 881-7355

Baltimore, MD 21201
900 Madison Avenue
Phone: (301) 962-3731

Boston, MA 02109
585 Commercial Street
Phone: (617) 223-5857

Brooklyn, NY 11232
850 Third Avenue
Phone: (212) 965-5754
(212) 965-5043

Buffalo, NY 14202
599 Delaware Avenue
Phone: (716) 846-4483
(716) 846-5452

Chicago, IL 60607
433 West Van Buren Street
1222 Main Post Office Building
Phone: (312) 353-7126

Cincinnati, OH 45202
1141 Central Parkway
Phone: (513) 684-3501

Cleveland, OH 44114
601 Rockwell Avenue, Room 463
Phone: (216) 522-4844

Columbus, OH 43215
New Federal Building
85 Marconi Boulevard, Room 231
Phone: (614) 469-7353

Dallas, TX 75201
500 South Ervay
Suite 470-B
Phone: (214) 767-5433

Denver, CO 80202
500 U.S. Customhouse
19th and California Streets
Phone: (303) 837-4915

Detroit, MI 48207
1560 East Jefferson Avenue
Phone: (313) 226-6260

East Orange, NJ 07018
20 Evergreen Place
Phone: (201) 645-6365
(201) 645-3265

Falls Church, VA 22046
701 W. Broad Street, Room 309
Phone: (703) 285-2578

Houston, TX 77009
1440 N. Loop, Suite 250
Phone: (713) 226-5581

Indianapolis, IN 46204
575 North Pennsylvania, Room 693
Phone: (317) 269-6500

Kansas City, MO 64106
1009 Cherry Street
Phone: (816) 374-3817

Los Angeles, CA 90015
1521 W. Pico Boulevard
Phone: (213) 688-4395

Miami, FL 33166
6501 N.W. 36th Street, Room 200
Phone: (305) 526-2920

Minneapolis, MN 55401
240 Hennepin Avenue
Phone: (612) 725-2121

Nashville, TN 37217
297 Plus Park Boulevard
Phone: (615) 251-7127

New Orleans, LA 70122
4298 Elysian Fields Avenue
Phone: (504) 589-2420

Omaha, NE 68102
1619 Howard Street
Phone: (402) 221-4675

Orlando, FL 32802
P.O. Box 118
Phone: (305) 855-0900

Philadelphia, PA 19106
900 U.S. Customhouse
2nd and Chestnut Streets
Phone: (215) 597-0837

Pittsburgh, PA 15220
7 Parkway Center, Suite 645
Phone: (412) 644-2858

San Antonio, TX 78204
419 S. Main, Room 301
Phone: (512) 229-6737

San Francisco, CA 94102
50 United Nations Plaza, Room 524
Phone: (415) 556-2062

San Juan, PR 00905
P.O. Box S4427
Old San Juan Station
Phone: (809) 753-4443

Seattle, WA 98174
909 First Avenue
Federal Office Building, Room 5003
Phone: (206) 442-5258

St. Louis, MO 63102
808 North Collins Street
Lacledes Landing
Phone: (314) 425-5021

Drugs

FDA ONGOING REVIEW OF OVER-THE-COUNTER (OTC) DRUG PRODUCTS ANPR

As part of its ongoing review of OTC drug products, FDA is issuing in the Federal Register of 1/5/82 advance notices of proposed rulemaking based on recommendations of the FDA Advisory Review Panel on Miscellaneous Internal Drug Products that would classify the following as:

Generally Recognized as Safe and Effective and Not Misbranded

Drug Products for the Treatment of Acute Toxic Ingestion
Docket No. 81N-0050, p. 444;

Smoking Deterrent Drug Products
Docket No. 0027, p. 490;

Orally-Administered Drug Products for the Treatment of Fever Blisters
Docket No. 81N-0060, p. 502;

Deodorant Drug Products for Internal Use
Docket No., 81N-0064, p. 512; and

Corn and Callus Remover Drug Products
Docket No. 81N-0122, p. 522;

and the following as:

Not Generally Recognized as Safe and Effective and as Being Misbranded

Insect Repellent Drug Products for Human Use
Docket No. 81N-0040, p. 424; and

Hormone-Containing Drug Products for Oral Use
Docket No. 81N-0144, p. 430.

Mercury-Containing Drug Products for Topical Antimicrobial Human Use
Docket No. 75N-0183, p. 436.

For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

Drugs

Drug Experience Report **NOA**

FDA is announcing the availability of the revised Drug Experience Report, Form FDA 1639, and instructions for completion of the form. This form is used by manufacturers and by health care professionals to report adverse drug experiences to FDA. Written comments on format or content to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857; requests for single copies of the revised form and further information to Judith Jones, Bureau of Drugs (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4580. Supplies of the form are available on written request from the Public Health Service Forms and Publications Distribution Center (HFA-268), 12100 Parklawn Dr., Rockville, MD 20857.
Docket No. 81N-0335 Federal Register 1/22/82 p. 3205

Proposed Recommendation to DEA Re Scheduling Status of THC **N**

FDA is announcing a proposed recommendation on the appropriate scheduling of tetrahydrocannabinol (THC) under the Controlled Substances Act (CSA). The document also includes a scientific and medical evaluation of THC. The proposed recommendation is published to give interested persons the opportunity to comment on the recommendation and on the scientific and medical evaluation. FDA will consider these comments in preparing its final recommendation on, and scientific and medical evaluation of, tetrahydrocannabinol before transmitting the information to the Assistant Secretary for Health of the Department of Health and Human Services (DHHS). The Assistant Secretary for Health is responsible for making the DHHS recommendation to the Drug Enforcement Administration (DEA). **Scheduling Recommendation:** FDA proposes to recommend to the Assistant Secretary for Health, DHHS, that THC remain in schedule I, but that if the new drug application (NDA) for THC marketing is approved by the agency, THC be rescheduled under the CSA to schedule II. **Comments by May 10, 1982,** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Edwin V. Dutra, Jr., Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.
Docket No. 81N-0168 Federal Register 3/9/82 p. 10080

Vitamin and Mineral Drug Products for Over-the-Counter Human Use **WANPR**

FDA is withdrawing a proposed monograph (an advance notice of proposed rulemaking) of March 16, 1979 that would have established conditions under which over-the-counter (OTC) vitamin and mineral drug products are generally recognized as safe and effective and not misbranded. The proposed monograph was based on recommendations of the FDA Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic Drug Products. The Agency is taking this action because the proposal did not discuss what effects legislation that was enacted in 1976 would have on the Agency's vitamin and mineral policies. Because of this omission, the proposal has been misinterpreted, resulting in considerable public confusion concerning the Agency's intention to regulate vitamin and mineral drug products. **Effective November 27, 1981.** For further information contact: Eileen Hodkinson, Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.
Docket No. 78N-0024 Federal Register 11/27/81 p. 57914

Drugs

Weight Control Drug Products for OTC Human Use **ANPR**

FDA is issuing an advance notice of a proposed rulemaking that would establish conditions under which over-the-counter (OTC) weight control drug products are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and is part of the ongoing review of OTC drug products conducted by FDA. **Written comments by May 27, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 81N-0022 Federal Register 2/26/82 p. 8466

Prescription Drug Products **PRFR**

FDA is proposing to revoke its final rule establishing requirements and procedures for the preparation and distribution of patient package inserts (PPIs) for prescription drug products for human use. On the basis of its further review of its PPI program, FDA believes the goals of providing patients with information about prescription drugs can be reached more effectively and efficiently by cooperating with health professionals and others in both the public and private sector to expand upon current initiatives in patient education, rather than by pursuing a more limited mandatory program through Federal regulations. For further information contact: Eileen Hodkinson, Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.
Docket No. 79N-0186 & 80N-0370 Federal Register 2/19/82 p. 7458

Topical Acne Drug Products for OTC Human Use; Establishment of a Monograph **ANPR**

FDA is issuing an advance notice of a proposed rulemaking that would establish conditions under which over-the-counter (OTC) acne drug products are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products and is part of the ongoing review of OTC drug products conducted by FDA. **Comments by June 21, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For Further Information Contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-4434960.
Docket No. 81N-0114 Federal Register 3/23/82 p. 12430

Topical Antifungal Drug Products for OTC Human Use; Establishment of a Monograph **ANPR**

FDA is issuing an advance notice of a proposed rulemaking that would establish conditions under which over-the-counter (OTC) antifungal drug products are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products and is part of the ongoing review of OTC drug products conducted by FDA. **Comments by June 21, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 80N-0476 Federal Register 3/23/82 p. 12480

Drugs

Digestive Aid Drug Products for OTC Human Use **ANPR**

FDA is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) digestive aid drug products (drugs for the treatment of the symptoms of immediate postprandial upper abdominal distress (IPPUAD), or drugs for the treatment of the symptoms of intestinal distress) are generally recognized as safe and effective and not misbranded. This notice is based on the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and is part of the ongoing review of OTC drug products conducted by FDA. **Comments by June 4, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.
Docket No. 81N-0106 Federal Register 1/5/82 p. 454
3/30/82 p. 13385

Foods

D&C Green No. 6; Listing as a Color Additive in Externally Applied Drugs and Cosmetics **FR**

FDA is "permanently" listing D&C Green No. 6 for use in externally applied drugs and cosmetics. This rule will remove all uses of this color additive in externally applied drugs and cosmetics from the provisional list on May 4, 1982. By a rule published in the Federal Register of March 27, 1981 (46 FR 18958), FDA removed all ingested uses of D&C Green No. 6 from the provisional list, but it did not address the disposition of existing stocks of the color. Therefore, this document also provides for the depletion of existing stocks of D&C Green No. 6 for all uses involving ingestion of the color additive. **Effective May 4, 1982. Objections by May 3, 1982** may be sent to the Dockets Management Branch (HFA-304), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. All affected products initially introduced or initially delivered for introduction into interstate commerce are required to fully comply by May 3, 1983. For general information contact: Garnett R. Higginbotham, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690. For information relating to the safety evaluation of D&C Green No. 6 contact Terry C. Troxell, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.
Docket No. 81N-0301 Federal Register 4/2/82 p. 14138

FD&C Red No. 40 **N**

FDA is announcing that the Working Group on FD&C Red No. 40 has submitted its final report on completed studies with FD&C Red No. 40 to the Director, Bureau of Foods, and to the Commissioner of Food and Drugs. The Working Group has concluded that the available data do not demonstrate that FD&C Red No. 40 is carcinogenic in rats and mice. The Working Group also has found no substantial question of safety regarding the current use of FD&C Red No. 40 and has determined that there is no need for additional safety testing at this time. **Address:** Copies of the report are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Andrew D. Laumbach, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW, Washington, DC 20204, 202-472-5690.
Docket No. 76N-0507 Federal Register 10/16/82 p. 51037

Foods

Carcinogenic Chemicals in Food and Color Additives **ANPR**

FDA is considering proposing a new policy for use in assuring the safe use of food additives and color additives that contain minor amounts of carcinogenic chemicals. This policy would replace the current case-by-case approach to regulating such additives with an approach that applies consistent standards. This advance notice describes the scientific and regulatory problems confronting the Agency with respect to such additives and explains the need to consider a change in FDA's present approach. This advance notice also discusses the alternatives that the Agency is considering.

FDA is publishing this advance notice so that the Agency will have the benefit of a broad range of views early in the rulemaking process, and so that interested persons will have an opportunity to express their opinions. Detailed regulations for implementing any policy that the Agency may adopt will be proposed in a future issue of the Federal Register after consideration of comments received in response to this advance notice.

In this issue of the Federal Register, the Agency is also publishing a final rule listing D&C Green No. 6 for use in externally applied drugs and cosmetics. That rule further explains and illustrates how FDA has applied the approach set forth in this advance notice of proposed rulemaking. This document also discusses alternative theories for implementing the approach that the Agency applied in the decision on D&C Green No. 6. **Comments by July 1, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information relating to the policy under consideration and regulations to be proposed contact: Terry C. Troxell, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690. For information relating to risk assessment procedures contact: Alan M. Rulis, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5676.
Docket No. 81N-0281 Federal Register 4/2/82 p. 14464

Reinstatement of Regulation for Aspartame **FR**

FDA is vacating the stay of effectiveness of the regulation for aspartame, and the regulation is reinstated. The Commissioner of Food and Drugs issued his Final Decision concerning the food additive petition for aspartame and determined that it has been shown to be safe for its proposed uses. **Effective October 22, 1981.** For further information contact: Theodore E. Herman, Regulations Policy Staff (HFC-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.
Docket No. 75F-0355 Federal Register 10/16/81 p. 50947

Common or Usual Names for Nonstandardized Foods **EED**

FDA is proposing to extend the period of time for compliance with the labeling requirements of the common or usual name established for diluted fruit or vegetable beverages for all affected products initially introduced or initially delivered for introduction into interstate commerce from July 1, 1982 to July 1, 1984. **Comments by May 25, 1982** to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Howard N. Pippin, Bureau of Foods (HHF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3092.
Docket No. 80N-0140 Federal Register 3/26/82 p. 13003

Foods

Stabilizers and Emulsifiers in Lowfat Milk and Skim Milk FR

FDA is staying the effective date of the provisions of the standards of identiy for lowfat milk and skim milk that would have required the phrase "with added milk solids not fat" to accompany the name of the food when either food is made to contain not less than 10 percent milk-derived nonfat solids. This stay has the effect of continuing the earlier requirement of the use of the terms "protein fortified" or "fortified with protein" until this labeling issue is resolved through a public hearing or other procedures. This stay is in response to objections filed on the December 12, 1980 final rule. **Effective March 16, 1982.** For further information contact: Eugene T. McGarrahan, Bureau of Foods (HFF-215), Food and Drug Administration, 200 C St. SW, Washington, DC 20204, 202-245-1155.
Docket No. 76N-0175 Federal Register 3/16/82 p. 11270

Frozen Desserts; Ice Cream, Frozen Custard, Ice Milk and Sherbet FR

FDA is amending the standards of identity for ice cream and frozen custard, ice milk, and sherbet to permit, in addition to sweet whey that is now permitted, the use of acid whey and modified whey products made from sweet and acid wheys as a source of whey solids. These whey sources may be used singly or in combination as long as the total whey solids do not exceed the maximum limits for whey solids allowed in the applicable frozen dessert standard. The maximum limits for total whey solids in these standardized frozen desserts remain unchanged. **Effective July 1, 1983,** for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance: November 3, 1981. Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Eugene T. McGarrahan, Bureau of Foods (HFF-215), Food and Drug Administration, 200 C St. SW, Washington, DC 20204, 202-245-1155.
Docket No. 78P-0374 Federal Register 9/4/81 p. 44432

Secondary Direct Food Additives; Ethyl Acetate FR

FDA amends the food additive regulations to provide for the safe use of ethyl acetate as a solvent in the decaffeination of coffee. This action is based on data contained in a petition filed by the General Foods Corp. **Effective January 5, 1982.** For further information contact: James B. Lamb, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW, Washington, DC 20204, 202-472-5690.
Docket No. 80F-0482 Federal Register 1/5/82 p. 145

Infant Formula Recall Requirements PR

FDA is proposing, in accordance with the Infant Formula Act of 1980, a recall regulation to be followed by infant formula manufacturers. This regulation would facilitate the removal from the marketplace of an infant formula product that does not provide the nutrients required by the Federal Food, Drug, and Cosmetic Act (the act) or which is otherwise adulterated or misbranded within the meaning of the act. For further information contact: John M. Taylor, Bureau of Foods (HFF-310), Food and Drug Administration, 200 C St. SW, Washington, DC 20204, 202-245-1186.
Docket No. 81N-0053 Federal Register 1/15/82 p. 2331

Foods

Iron Fortification of Enriched Bread and Flour; Standards of Identity FR

FDA is confirming the effective date for compliance with all provisions of the amended standards of identity for enriched bread, rolls, buns; enriched flour; and enriched self-rising flour, published in the Federal Register of August 28, 1981. (The amendment removed minimum and maximum requirements for iron enrichment and established single-level requirements of 12.5 milligrams per pound for enriched bread, rolls, and buns; and 20 milligrams per pound for enriched flour and enriched self-rising flour to promote greater uniformity and to allow enriched bread to be made from enriched flour without further adjustment.) **Effective July 1, 1983,** for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance may have begun on October 27, 1981. For further information contact: F. Leo Kauffman, Bureau of Foods (HFF-214), Food and Drug Administration, 200 C St. SW, Washington, DC 20204, 202-245-1164.
Docket No. 79N-0327 Federal Register 2/12/82 p. 6425

Rennet Casein; Memorandum of Understanding With the Royal Norwegian Ministry of Agriculture N

FDA has executed a memorandum of understanding with the Royal Norwegian Ministry of Agriculture. The purpose of the understanding is to improve the compliance status of rennet casein exported from Norway to the United States, and to minimize the need for extensive FDA audit sampling of certified rennet casein from Norway. **Effective February 26, 1982.** For further information contact: Walter J. Kustka, Intergovernmental and Industry Affairs Staff (HFC-50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1580.
MOU-FDA-225-82-2001 Federal Register 4/9/82 p. 15414

PCBs in Fish and Shellfish; Reduction of Tolerances N

FDA announces the availability of the Initial Decision of the Administrative Law Judge. **Addresses:** Copies of the Initial Decision are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Theodore E. Herman, Regulations Policy Staff (HFC-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.
Docket No. 77N-0080 Federal Register 3/9/82 p. 10079

Fresh or Fresh-Frozen Bivalve Mollusca Destined for the United States N

FDA has executed a memorandum of understanding (MOU) with the Secretariat of Health and Welfare, United States of Mexico. The purpose of the memorandum is to affirm their intention to cooperate in assuring that fresh and fresh-frozen bivalve mollusca (oysters, clams, and mussels) exported to the United States conform to certain regulations (sanitation and labeling). This revised MOU replaces the memorandum that was signed March 7, 1979. **Effective October 15, 1981.** For further information contact: Walter J. Kustka, Interagency and Industry Affairs Staff (HFC-50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1583.
FDA 225-79-4009 Federal Register 12/1/81 p. 58366

General

Administrative Practices and Procedures; Reimbursement for Participation FR

FDA is removing the regulations which established a pilot program for reimbursement of public participants in certain FDA administrative proceedings. The pilot reimbursement program is being terminated because the United States Court of Appeals for the Fourth Circuit held that FDA does not have authority to reimburse public participation in its administrative proceedings. **Effective March 26, 1982.** For further information contact: Alexander Grant, Office of Consumer Affairs (HFE-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5006. Docket No. 76P-0126 Federal Register 3/26/82 p. 12951

Radiological Health

Public Advisory Committees: Request for Nominations of Voting Members N

FDA is requesting nominations for membership on the Medical Radiation Advisory Committee. Four vacancies will occur on June 30, 1982. Nominations must be submitted by April 23, 1982 to the Bureau of Radiological Health (HFX-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. For further information contact: Gordon C. Johnson at the address given above (301-443-6220). The function of the Medical Radiation Advisory Committee is to advise the Commissioner of Food and Drugs on the formulation of policy and development of a coordinated national program relating to application of radiation to obtain maximum diagnostic information and therapeutic benefit per unit of radiation exposure to the public.

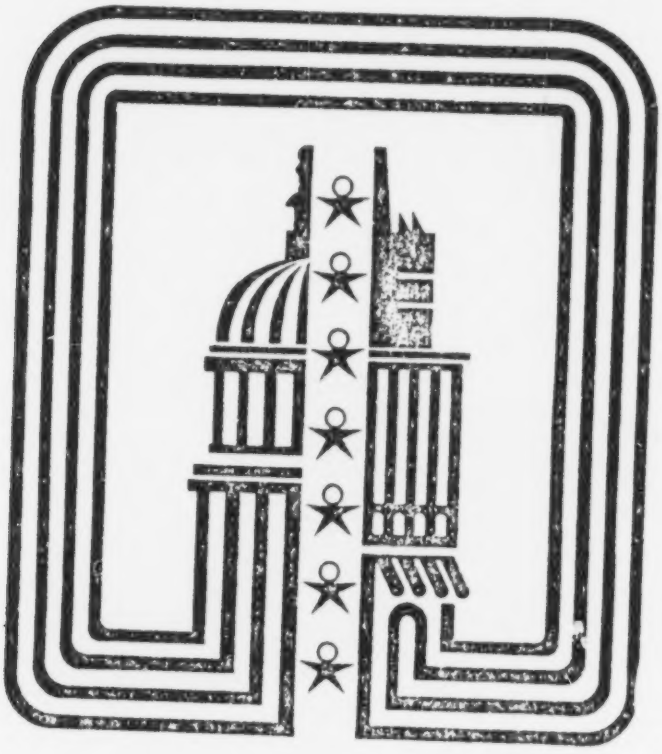
Among its current activities, the committee reviews qualifications of operators of radiation devices; reviews radiological training and education programs; advises on radiation devices guidelines and standards; and considers efficacy in relation to the selection and character of medical and dental uses of radiation.

The committee consists of 13 members including the chairperson. Members are selected and appointed by the Secretary of Health and Human Services from those nominees who have expertise appropriate to the work of the committee in one or more fields of medicine, dentistry, health sciences, biomedical engineering, public health, or related technology. For the 1982 membership, the Medical Radiation Advisory Committee will have particular need for candidates with knowledge of medical diagnosis and decisionmaking, diagnostic imaging technology, and health care delivery.

FDA has a special interest in assuring that women, minority groups, and the physically handicapped are adequately represented on advisory committees and therefore extend particular encouragement to nominations for appropriately qualified female, minority, and physically handicapped candidates.

Any interested person may nominate one or more qualified persons for membership. A complete curriculum vitae of the nominees shall state that the nominee is aware of the nomination, is willing to serve as a member of the committee, and appears to have no conflict of interest that would preclude committee membership. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

NATIONAL CONSUMERS WEEK



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